PrEP to Prevent HIV and Promote Sexual Health

May 2022

Table 1: Comparison of Key Clinical and Logistical Factors in Choosing a PrEP Regimen (details provided in discussion that follows; also see Appendix: Care Provider Checklists for PrEP Initiation, Regimen Choice, and Follow-Up)

TDF/FTC (tenofovir disoproxil fumarate/emtricitabine; Truvada)	**TAF/FTC** (tenofovir alafenamide/ emtricitabine; Descovy)	**CAB LA** (long-acting injectable cabotegravir; Apretude)	**Comments**
Efficacy			
All exposures, including sexual and injection drug use	• Sexual exposures in cisgender MSM, transgender women, and adolescents weighing ≥35 kg [a] • Not approved for receptive vaginal sexual exposure • Not approved for injection drug exposure	• Sexual exposures in all adults and adolescents weighing ≥35 kg • Not approved for injection drug exposure	A 2017 amendment to the NYCRR grants minors capacity to consent to PrEP and PEP without parental/guardian involvement
Time to Protection [b]			
• Rectal exposure: 7 days of daily dosing • Genital and blood exposure: 7 days of daily dosing, with maximal protection after 20 days • Cisgender MSM: After 2 doses taken 2 to 24 hours before risk exposure	No data	No data	—
Renal Safety			
• Do not initiate if CrCl <60 mL/min • Discontinue if confirmed CrCl <50 mL/min • Potential effect on renal tubular function; meta-analysis shows good safety [c]	• Improved renal biomarkers compared with TDF • Can be used if CrCl ≥30 mL/min in MSM and transgender women • Do not initiate if CrCl <30 mL/min	Increased monitoring for adverse effects is recommended with CrCl <30 mL/min	• Inform patients with risk factors of the increased possibility of kidney disease with TDF/FTC or TAF/FTC as PrEP; weigh risks and benefits • More frequent monitoring may be required for patients at increased risk of renal disease (i.e., hypertension, diabetes, >40 years old)

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Bone Safety			
Potential decrease in bone mineral density; meta-analysis shows good safety [c]	• Favorable bone biomarkers compared with TDF • Preferred regimen for cisgender men and transgender women with osteoporosis	Preferred option for prevention of sexual exposures in all individuals with osteopenia or osteoporosis	Inform patients with preexisting risk factors or documented osteopenia, osteomalacia, or osteoporosis of the risk of bone loss with TDF/FTC; weigh the risks and benefits
Weight and LDL Cholesterol			
• Weight neutral • Small decreases in LDL	• Mild weight gain was observed in studies • Small increases in LDL	• Mild weight gain was observed in MSM and transgender women • No significant effect on lipids	—
Dosing			
• Daily dosing is preferred • On-demand dosing is an option in cisgender MSM	Daily dosing only	• Optional 30-day oral lead-in • First 2 IM injections are administered 4 weeks apart; thereafter, injections are given every 2 months	—
Same-Day Initiation			
Generic TDF/FTC is a preferred insurance option and is usually available for same-day initiation	May require prior authorization	• May require prior insurance authorization for oral or injectable CAB • Implementation challenges may interfere	—
Common Adverse Effects			
Diarrhea (6%), nausea (5%) [d]	Diarrhea (5%), nausea (4%) [e]	Injection site reactions (32% to 81%) [f], which are mostly mild and greatest initially	—
Use During or When Planning Pregnancy			
• Can be used. Weigh risks and benefits in shared decision-making • May be continued through pregnancy and breastfeeding • Prospectively report information regarding the use of TDF/FTC as PrEP during pregnancy to the Antiretroviral Pregnancy Registry	Do not use for vaginal exposure; no data in pregnancy	• If attempting to conceive or if pregnancy occurs, continue only if the expected benefit justifies the potential risk to the fetus • Recommend TDF/FTC if it is an appropriate option for patients who wish to continue PrEP	• HIV acquisition risk is increased during pregnancy and is highest late in pregnancy and early postpartum • Suppressive ART (TasP) for a partner with HIV is important for risk reduction • Acute seroconversion significantly increases the risk of perinatal transmission during pregnancy and while breastfeeding

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Use With Oral Contraceptives			
No interaction expected based on PK data	Not for use as PrEP for vaginal sexual exposure	No interaction expected based on PK data	—
Use With Gender-Affirming Hormones			
• Does not alter estrogen levels • Does not alter testosterone levels in transgender men • Estrogen may lower tenofovir levels, but levels achieved with daily dosing are protective	No data; no interaction expected based on PK profiles and lack of significant interactions with oral contraceptives	No data; no interaction expected based on PK profiles and lack of significant interactions with oral contraceptives	—
Patients With Active Chronic HBV [g,h]			
• Active against and FDA-approved for treatment of HBV infection • Daily dosing required when used for PrEP and HBV treatment	• Active against and FDA-approved for treatment of HBV infection • Daily dosing required when used for PrEP and HBV treatment	Not active against HBV infection	Monitor closely for rebound HBV viremia if TDF/FTC or TAF/FTC is discontinued in a patient with chronic HBV infection
Drug-Drug Interactions			
See NYSDOH AI Resource: ART Drug-Drug Interactions > TDF and TAF Interactions	See NYSDOH AI Resource: ART Drug-Drug Interactions > TDF and TAF Interactions	See NYSDOH AI Resource: ART Drug-Drug Interactions > CAB Interactions	—
Generic Formulation Availability			
Generic TDF/FTC is available	Brand only	Brand only	TAF/FTC and CAB may require prior insurance authorization

Abbreviations: 3TC, lamivudine; ART, antiretroviral therapy; CAB, cabotegravir; CrCl, creatinine clearance; FDA, U.S. Food and Drug Administration; FTC, emtricitabine; HBV, hepatitis B virus; IM, intramuscular; LDL, low-density lipoprotein; MSM, men who have sex with men; NYCRR, New York Codes, Rules and Regulations; PEP, post-exposure prophylaxis; PK, pharmacokinetic; PrEP, pre-exposure prophylaxis; TAF, tenofovir alafenamide; TasP, treatment-as-prevention; TDF, tenofovir disoproxil fumarate.

Notes:

a. Transgender women made up only 1% of the DISCOVER study population [Mayer, et al. 2020].
b. Time to protection has not been definitively established for any available PrEP regimen (see guideline section Choosing and Prescribing a PrEP Regimen > Time to Protection, below).
c. [Pilkington, et al. 2018]
d. [Glidden, et al. 2016]
e. [Mayer, et al. 2020]
f. [Delany-Moretlwe, et al. 2022; Landovitz, et al. 2021]
g. TDF and TAF are approved by the FDA as treatment for HBV. FTC is also active against HBV but is not FDA-approved for HBV treatment. TDF or TAF in combination with FTC or 3TC (which is FDA-approved for HBV treatment and is molecularly similar to FTC) is commonly used in patients with HIV/HBV coinfection as part of an ART regimen to treat both infections.
h. Evaluate individuals with chronic HBV who are not PrEP candidates for recommended treatment (see NYSDOH AI guideline Prevention and Management of Hepatitis B Virus Infection in Adults With HIV).

References

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