

PREFERRED Initial ART Regimens for Nonpregnant Adults (listed alphabetically)		Regimen (rating)	Comments
Available as a Single-Tablet Formulation			
ABC/3TC/DTG (A1)	[Truimeq]	Initiate only in patients confirmed to be negative for HLA-B*57:01, including when a "rapid-start" or "test-and-treat" initiation of ART occurs before baseline laboratory test results are available. Initiate only in patients with CrCl ≥ 50 mL/min. Consider underlying risk of coronary heart disease. Documented DTG resistance after initiation in treatment-naïve patients is rare. Take magnesium- or aluminum-containing antacids 2 hours before or 6 hours after DTG, calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	
TAF 25 mg/FTC/BIC (A1) [Biktarvy]		Initiate only in patients with CrCl ≥ 30 mL/min. Contains 25 mg of TAF, unboosted. Take magnesium- or aluminum-containing antacids 2 hours before or 6 hours after BIC, calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	
TAF 25 mg/FTC and DTG (A1) [Descovy and Tivicay]		Initiate only in patients with CrCl ≥ 30 mL/min. Documented DTG resistance after initiation in treatment-naïve patients is rare. Contains 25 mg of TAF, unboosted. Take magnesium- or aluminum-containing antacids 2 hours before or 6 hours after DTG, calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.	
Available as Multi-Tablet Regimen with Once-Daily Dosing			
TAF 25 mg/FTC and RAL HD (A2) [Descovy and Isentress HD]		Initiate only in patients with CrCl ≥ 30 mL/min. To date, no clinical trials have been conducted with TAF and RAL; data are based on bioequivalence pharmacokinetic studies. Contains 25 mg of TAF, unboosted. Administer as TAF/FTC once daily and RAL HD 1200 mg once daily, dosed as two 600 mg HD tablets. Magnesium- or aluminum-containing antacids are contraindicated; co-administration of calcium-containing antacids is not recommended with RAL HD.	
Additional abbreviation: CrCl, creatinine clearance.			
ART regimens for individuals of childbearing potential: Refer to the DHHS guideline: Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States.			
Substitutions: 1) In all cases, FTC and 3TC are interchangeable; 2) TAF 10 mg and TAF 25 mg are interchangeable.			
Dose adjustments: Refer to Table 8: ARV Dose Adjustments for Renal and Hepatic Impairment in the full guideline.			

ALL RECOMMENDATIONS (continued from P.1)

P.2

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SELECTING AN INITIAL ART REGIMEN

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE JANUARY 2019 UPDATE

Note: The recommendations in this guideline pertain to initial ART regimens for adults with HIV who are *not pregnant*.

Dolutegravir (DTG) Safety Statement, May 2018

On May 18, 2018, the FDA and the DHHS Antiretroviral Guidelines Panels issued statements in response to preliminary results from a study that reported increased risk of neural tube defects in babies born to mothers taking DTG-based ARV drug regimens at the time of conception.

Until more data become available, **DTG-containing regimens should be avoided in any HIV-exposed individual who is pregnant in the first trimester or could become pregnant and is not using effective contraception.** If there are no alternatives to DTG for individuals of childbearing potential, then clinicians should strongly advise the use of effective contraception and should obtain a pregnancy test before initiating treatment.

For more information, see: *DHHS Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*

ALL RECOMMENDATIONS

P.1

- Clinicians should involve their patients when deciding which ART regimen is most likely to result in adherence. (A3)
- Clinicians should perform the following when initiating ART: 1) Assessment for comorbidities and chronic co-administered medications that may affect the choice of regimen for initial therapy (A3); 2) Genotypic resistance testing should be performed at diagnosis, or at the initial visit if not done previously, for the protease (A2), reverse transcriptase (A2), and integrase (B2) genes.

Continued on P.2 →

CONTRAINDICATED ART Regimens Based on Routine Baseline [a] Laboratory Parameters

Lab Parameter	Contraindicated ART Regimens
Viral load $\geq 100,000$ copies/mL	<ul style="list-style-type: none"> ABC/3TC and COBI/ATV (Epzicom and Evotaz) ABC/3TC and EFV (Epzicom and Sustiva) ABC/3TC and RTV and ATV (Epzicom and Norvir and Reyataz) TAF/FTC/RPV (Odefsey) TDF/FTC/RPV (Complera)
CD4 < 200 cells/mm ³	<ul style="list-style-type: none"> TAF/FTC/RPV (Odefsey) TDF/FTC/RPV (Complera)
CrCl < 50 mL/min	<ul style="list-style-type: none"> ABC/3TC (Epzicom) ABC/3TC/DTG (Truimeq) TDF/3TC/DOR (Delstrigo) TDF/FTC/EFV (Atripla) TDF/FTC/RPV (Complera)
CrCl < 30 mL/min	<ul style="list-style-type: none"> TAF/FTC (Descovy) TAF/FTC/BIC (Biktarvy) TAF/FTC/COBI/DRV (Symtuza) TAF/FTC/COBI/EVG (Genvoya) [b] TAF/FTC/RPV (Odefsey) TDF/FTC (Truvada)

Additional abbreviation: CrCl, creatinine clearance.

Notes:

- For renal adjustment of fixed-dose combinations and single-tablet regimens while on therapy, see Table 8: ARV Dose Adjustments for Renal and Hepatic Impairment in full guideline.
- Unless CrCl < 15 mL/min and on chronic hemodialysis.

DRUG NAME ABBREVIATION KEY: 3TC: lamivudine; ABC: abacavir; ATV: atazanavir; BIC: bictegravir; COBI: cobicistat; DOR: doravirine; DRV: darunavir; DTG: dolutegravir; EFV: efavirenz; EVG: elvitegravir; FTC: emtricitabine; RAL: raltegravir; RPV: rilpivirine; RTV: ritonavir; TAF: tenofovir alafenamide; TDF: tenofovir disoproxil fumarate

KEY POINTS

- INSTI-based regimens are generally the best choice for most individuals because of tolerability and durability.
- Neither mental health nor substance use disorders are contraindications to initiating therapy. In some special cases, delay of initiation (for as short a time as possible) may be appropriate while addressing adherence issues and/or possible interactions (see the NYSDOH AI guideline *When to Initiate ART*).
- Both COBI and DTG can cause decreased tubular excretion of creatinine and may cause a slight increase in measured creatinine.
- ABC has been associated with a higher risk of myocardial infarction in some studies, although not in others. No clear causal link has been established.
- Boosted PIs and COBI-boosted EVG are associated with a higher incidence of hyperlipidemia than unboosted integrase strand transfer inhibitors.
- Consultation with an experienced HIV care provider is advised when a patient's baseline viral load is very high (>750,000 copies/mL).
- When initiating therapy at the time of diagnosis ("rapid start") it is not necessary to have the results of baseline laboratory tests immediately available. Labs should be ordered at the time of initiation of ART, and any necessary adjustments to therapy should be made as soon as the results are available (such as for renal function or evidence of resistance). ABC-containing regimens should not be used for rapid start without documentation of negative HLA-B*5701 test results.

Select Drug-Drug Interactions to Discuss before Initiating ART in Treatment-Naive Patients

Drugs	ARV(s): Comments
H ₂ -blockers	<p>ATV: In treatment-naive patients on boosted ATV, H₂-blockers should be taken simultaneously with ATV or, if simultaneous dosing is not possible, separated from ATV by 10 hours; prescribe no more than 20 mg of famotidine or equivalent for 1 dose and no more than 40 mg twice daily of famotidine or equivalent for daily dose.</p> <p>RPV: Use with caution; administer at least 12 hours before or at least 4 hours after RPV.</p>
Inhaled steroids Statins	<p>COBI; RTV: Alternatives or dose adjustments may be needed. Consult the package inserts for drug-drug interactions between specific statins and ARVs.</p>
Polyvalent cations [a]	<p>DTG; BIC: Take 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.</p> <p>RAL: Magnesium- or aluminum-containing antacids are contraindicated; calcium-containing antacids are acceptable.</p> <p>RAL HD: Magnesium- or aluminum-containing antacids are contraindicated; co-administration of calcium-containing antacids is not recommended.</p> <p>EVG: Separate dosing by 2 hours, either before or after dose of EVG.</p>
PPIs	<p>ATV: Contraindicated with ATV in treatment-experienced patients; in treatment-naive patients, use no more than equivalent of 20 mg of omeprazole with ATV, separated by 12 hours.</p> <p>RPV: Contraindicated.</p>
Metformin	<p>DTG: Metformin levels are significantly raised when co-administered with DTG. If used concomitantly, total daily dose of metformin should not exceed 1,000 mg without clinical evaluation of efficacy and adverse events.</p>
Ethinyl estradiol and norethindrone [b]	<p>EFV; COBI/ATV; COBI/DRV; RTV and DRV: Use alternative or additional (e.g., barrier) contraceptive methods or choose alternative ART regimen.</p> <p>ATV; RTV and ATV: Use with caution; see manufacturer's package insert for specific dosing information.</p>
Factor Xa inhibitors	<p>COBI; RTV:</p> <ul style="list-style-type: none"> - Apixaban: Reduce dose by 50% if patient is on 5 mg twice daily; avoid use if the indicated dose is 2.5 mg twice daily (based on age, weight, creatinine level). - Dabigatran: No adjustment needed if CrCl ≥50 mL/min; avoid if CrCl <50 mL/min. - Rivaroxaban: Avoid use.
Platelet inhibitors	<p>COBI; RTV:</p> <ul style="list-style-type: none"> - Clopidogrel: Avoid use. - Prasugrel: No adjustment needed. - Ticagrelor: Avoid use.

Additional abbreviations: CrCl, creatinine clearance; PPI, proton-pump inhibitor.

Notes:

- Aluminum, calcium, magnesium, or iron in some antacids or vitamin preparations.
- For emergency contraception, other oral combinations, and patch, ring, or injectable formulations, please refer to package insert for specific ARV for dosing instructions and safety information.

ALTERNATIVE Initial ART Regimens for Nonpregnant Adults (listed alphabetically)

Regimen (rating)	Comments
<i>Available as a Single-Tablet Formulation</i>	
TAF 10 mg/FTC/COBI/DRV (B2) [Symtuza]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥30 mL/min. • Carefully consider drug-drug interactions with COBI. • Contains 10 mg TAF, boosted.
TAF 10 mg/FTC/COBI/EVG (B1) [Genvoya]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥30 mL/min. • Carefully consider drug-drug interactions with COBI. • Contains 10 mg of TAF, boosted with COBI. • Separate dosing of antacids by 2 hours, either before or after dose of EVG.
TAF 25 mg/FTC/RPV (B3) [Odefsey]	<ul style="list-style-type: none"> • Initiate only in patients confirmed to have a CD4 cell count ≥200 cells/mm³ and viral load <100,000 copies/mL. • When a "rapid-start" or "test-and-treat" initiation of ART occurs before a patient's viral load and CD4 count are available, avoid use of RPV. • Initiate only in patients with CrCl ≥30 mL/min. • Use with caution in patients with depression or a history of suicidality. • To date, no clinical trials have been conducted; data are based on bioequivalence pharmacokinetic studies of TAF compared with TDF. • Contraindicated with PPIs. • Use H₂-blockers with caution and separate dosing by 12 hours. • Must take with food. • Contains 25 mg of TAF, unboosted.
TDF/3TC/DOR (B1) [Delstrigo]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥50 mL/min. • Contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers. • Consider bone mineral density.
<i>Available as Multi-Tablet Regimen with Once-Daily Dosing</i>	
ABC/3TC and DOR (B2) [Epzicom and Pifeltro]	<ul style="list-style-type: none"> • Initiate only in patients confirmed to be negative for HLA-B*5701. • When a "rapid-start" or "test-and-treat" initiation of ART occurs before baseline laboratory test results are available, avoid use of ABC until a patient's HLA-B*5701 test is confirmed negative. • Consider underlying risk of coronary heart disease. • Contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers.
TAF 25 mg/FTC and DOR (B2) [Descovy and Pifeltro]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥30 mL/min. • Contraindicated when co-administered with drugs that are strong CYP3A enzyme inducers.
TDF/FTC and DTG (B1) [Truvada and Tivicay]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥50 mL/min. • Documented DTG resistance after initiation in treatment-naive patients is rare. • Consider bone mineral density. • Take magnesium- or aluminum-containing antacids 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
TDF/FTC and RAL HD (B1) [Truvada and Isentress HD]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥50 mL/min. • Consider bone mineral density. • Administer as TDF/FTC once daily and RAL HD 1200 mg once daily, dosed as two 600 mg HD tablets. • Magnesium- or aluminum-containing antacids are contraindicated; co-administration of calcium-containing antacids is not recommended with RAL HD.
<i>Available as Multi-Tablet Regimen with Twice-Daily Dosing</i>	
TAF 25 mg/FTC and RAL (B3) [Descovy and Isentress]	<ul style="list-style-type: none"> • Initiate only in patients with CrCl ≥30 mL/min. • Administer as ABC/3TC once daily and RAL 400 mg twice daily. • Magnesium- or aluminum-containing antacids are contraindicated; calcium-containing antacids are acceptable with RAL.

• **Additional abbreviations:** CrCl, creatinine clearance; PPI, proton-pump inhibitor.

• **ART regimens for individuals of childbearing potential:** Refer to the DHHS guideline: *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*.

• **Substitutions:** 1) In all cases, FTC and 3TC are interchangeable; 2) TAF 10 mg and TAF 25 mg are not interchangeable; 3) COBI and RTV should not be considered interchangeable because of their drug-interaction profiles.

• **Dose adjustments:** Refer to Table 8: *ARV Dose Adjustments for Renal and Hepatic Impairment* in the full guideline.



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