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KEY POINTS

Special Considerations

- Neither mental health nor substance use disorders are contraindications to initiating ART. In some special cases, delay of initiation (for as short a time as possible) may be appropriate while addressing adherence issues and possible interactions.
- Both COBI and DTG can cause decreased tubular excretion of creatinine and may cause a slight increase in measured creatinine.
- Although no clear causal link has been established, ABC use has been associated with an increased risk of adverse cardiovascular events in multiple studies, including large cohorts and clinical trials, and should be avoided in an initial ART regimen.
- Boosted protease inhibitors 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 (HIV RNA level > 750,000 copies/mL).

ART–Initiation Laboratory Testing

- When initiating ART at the time of HIV diagnosis (rapid start), it is not necessary to have the results of baseline laboratory tests immediately available. Laboratory tests 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 a documented negative HLA–B*57:01 test result.

ALL RECOMMENDATIONS (continued from P.1)

Regimen Selection, continued

- With the exception of DTG/3TC, clinicians should not prescribe 2–drug regimens as initial ART. (A3) Clinicians should prescribe DTG/3TC only after:
 - HIV resistance and hepatitis B virus status are known. (A1)
 - Genotypic resistance testing results have confirmed that a patient does not have a relevant reverse transcriptase mutation, including the M184V/I resistance mutation. DTG/3TC is contraindicated in patients with these resistance–associated mutations. (A1)
- Clinicians should consult with an experienced HIV care provider when selecting an initial ART regimen for a patient who has:
 - Baseline genotypic testing results indicating the need for an ART regimen other than the available preferred or alternative regimens. (A3)
 - Extensive comorbidities, including metabolic complications and obesity; or active opportunistic infections. (B3)
 - The NYSDOH Clinical Education Initiative provides access to HIV specialists through their toll–free line: 866–637–2342.

Follow-up


- Clinicians or clinical support staff should follow up by telephone or other methods, preferably within 2 weeks after treatment initiation, to assess tolerance and adherence; adherence should be reinforced at regular intervals. (A3)
- Clinicians should obtain a viral load test within 4 weeks after ART initiation to assess initial response to therapy. (A3)

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; RAL HD: RAL high–dose; RPV: rilpivirine; RTV: ritonavir; TAF: tenofovir alafenamide; TDF: tenofovir disoproxil fumarate

Selected Drug–Drug Interactions to Discuss Before Initiating ART in Treatment–Naïve Patients	
Drug Class	ARV(s): Comments
H ₂ -blockers	ATV: In treatment–naïve patients on boosted ATV, H ₂ -blockers should be taken simultaneously with ATV/RTV with food. If simultaneous dosing with food is not possible, ATV/RTV should be taken at least 10 hours after the H ₂ -blocker. H ₂ -blocker doses should not exceed the equivalents of 40 mg famotidine twice daily for ART–naïve patients or 20 mg famotidine twice daily for ART–experienced patients. RPV: Use with caution; administer H ₂ -blockers at least 12 hours before or at least 4 hours after RPV.
Inhaled steroids Statins	COBI; RTV: Alternatives or dose adjustments may be needed. Consult the package inserts for drug–drug interactions between specific statins and ARVs.
Polyvalent cations [a]	BIC; DTG: Take 2 hours before or 6 hours after DTG; calcium–containing antacids or iron supplements may be taken simultaneously if taken with food. RAL: Magnesium– or aluminum–containing antacids are contraindicated; calcium–containing antacids are acceptable. RAL HD: Magnesium– or aluminum–containing antacids are contraindicated; coadministration of calcium–containing antacids is not recommended. EVG: Separate dosing by 2 hours, either before or after dose of EVG.
Proton pump inhibitors	ATV: Contraindicated with ATV in treatment–experienced patients; in treatment–naïve patients, use no more than equivalent of 20 mg of omeprazole with ATV, separated by 12 hours. RPV: Contraindicated.
Metformin	DTG: Metformin levels are significantly raised when coadministered with DTG. If used concomitantly, the total daily dose of metformin should not exceed 1,000 mg without clinical evaluation of efficacy and adverse events.
Ethinyl estradiol and norethindrone [b]	ATV/COBI; DRV/COBI; DRV/RTV; EFV: Use alternative or additional (e.g., barrier) contraceptive methods or choose alternative ART regimen. ATV; ATV/RTV: Use with caution; see manufacturer's package insert for specific dosing information.
Factor Xa inhibitors	COBI; RTV: – 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	COBI; RTV: – Clopidogrel: Avoid use. – Prasugrel: No adjustment needed. – Ticagrelor: Avoid use.
Additional abbreviation: CrCl, creatinine clearance. Notes: a) Aluminum, calcium, magnesium, or iron in some antacids or vitamin preparations. b) For emergency contraception, other oral combinations, and patch, ring, or injectable formulations, please refer to the package insert for specific ARV for dosing instructions and safety information.	

HIV CLINICAL RESOURCE 1/4-FOLDED GUIDE

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SELECTING AN INITIAL ART REGIMEN

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE MARCH 2025

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

Dolutegravir (DTG) Safety Statement, May 2021

The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while using DTG was removed. DTG has been shown to be safe throughout pregnancy. For more information, see Use of Dolutegravir in Individuals of Childbearing Capacity at hivguidelines.org/dtg

ALL RECOMMENDATIONS P.1

Regimen Selection

- When selecting an initial ART regimen for treatment naïve–patients, clinicians should:
 - Perform genotypic HIV resistance testing results for protease (A2), reverse transcriptase (A2), and integrase (B2) genotypic resistance if the testing has not already been performed or results are not otherwise available.
 - Inform patients of the regimen options and engage in shared decision–making to optimize the likelihood of adherence. (A3)
 - Assess for comorbidities and chronic coadministered medications that may affect the choice of regimen for a patient's initial ART. (A3)
 - Choose a preferred ART regimen unless one of the alternative regimens is a better choice based on individual patient factors. (A1)
 - Recommend a single–tablet regimen or a regimen with once–daily dosing unless those regimens are contraindicated by HIV resistance, drug–drug interactions, intolerance, allergy, or access. (A2)
 - Ask patients about their reproductive plans and discuss the use of contraception. (A3)
 - Note: In choosing an initial ART regimen for a patient who is pregnant or planning a pregnancy, refer to DHHS Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States.

Continued on P.2 →

PREFERRED Initial ART Regimens for Nonpregnant Adults (listed alphabetically)	
Regimen (rating)	Comments
<i>Available as a Single-Tablet Formulation</i>	
DTG/3TC (A1) [Dovato]	<ul style="list-style-type: none"> Initiate only in patients with CrCl ≥ 30 mL/min. Do not use in patients with HBV coinfection. Do not initiate before HIV resistance tests results are available. Do not initiate in patients with NRTI resistance, including the M184V/I mutation. Do not initiate in patients with baseline HIV RNA levels $>500,000$ copies/mL until additional study data are available. Documented DTG resistance after initiation in treatment-naïve patients is rare. Magnesium- or aluminum-containing antacids may be taken 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]	<ul style="list-style-type: none"> Initiate only in patients with CrCl ≥ 30 mL/min. Contains 25 mg of TAF, unboosted. Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after BIC; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
<i>Available as Multi-Tablet Regimen with Once-Daily Dosing</i>	
TAF 25 mg/FTC or TDF 300 mg/ FTC and DTG (A1) [Descovy or Truvada and Tivicay]	<ul style="list-style-type: none"> For TAF/FTC, initiate only in patients with CrCl ≥ 30 mL/min. Contains 25 mg of TAF, unboosted. For TDF/FTC, initiate only in patients with CrCl ≥ 50 mL/min. For TDF/FTC, use with caution in patients with or at risk for osteoporosis. Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food. Documented DTG resistance after initiation in treatment-naïve patients is rare.
<ul style="list-style-type: none"> Additional abbreviations: CrCl, creatinine clearance; HBV, hepatitis B virus; NRTI, nucleoside reverse transcriptase inhibitor. ART regimens for individuals of childbearing potential: Refer to DHHS: Recommendations for the Use of Antiretroviral Drugs During Pregnancy 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. Dose adjustments: Refer to ARV Dose Adjustments for Hepatic or Renal Impairment section in full guideline. 	

CONTRAINDICATED ART Regimens Based on Routine Baseline Laboratory Parameters	
Lab Parameter	Contraindicated ART Regimens
HIV RNA level $\geq 100,000$ copies/mL	<ul style="list-style-type: none"> 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/DTG (Trisemeq) TDF/3TC/DOR (Delstrigo) TDF/FTC/EFV (Atripla) TDF/3TC/EFV (Symfi and Symfi Lo) TDF/FTC/RPV (Complera)
CrCl <30 mL/min	<ul style="list-style-type: none"> TAF/FTC (Descovy) TAF/FTC/BIC (Biktarvy) [a] TAF/FTC/DRV/COBI (Symtuza) TAF/FTC/EVG/COBI (Genvoya) [b] TAF/FTC/RPV (Odefsey) TDF/FTC (Truvada) DTG/3TC (Dovato)
<ul style="list-style-type: none"> Additional abbreviation: CrCl, creatinine clearance. Dose adjustments: Refer to ARV Dose Adjustments for Hepatic or Renal Impairment section in full guideline. Note: a) Unless CrCl <15 mL/min and on chronic hemodialysis. 	

ALTERNATIVE Initial ART Regimens for Nonpregnant Adults (listed alphabetically)	
Regimen (rating)	Comments
<i>Available as a Single-Tablet Formulation</i>	
TAF 10 mg/FTC/DRV/COBI (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/EVG/COBI (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 cation-containing (calcium, aluminum, magnesium) 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 count ≥ 200 cells/mm³ and HIV RNA level $<100,000$ copies/mL. Avoid use of RPV in a rapid-start or test-and-treat regimen if a patient's viral load and CD4 count results are not available. 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 for initial therapy; data are based on bioequivalence pharmacokinetic studies of TAF compared with TDF. Contraindicated with proton pump inhibitors. 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 coadministered with drugs that are strong CYP3A enzyme inducers. Use with caution in patients with or at risk for osteoporosis.
<i>Available as Multi-Tablet Regimen with Once-Daily Dosing</i>	
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 coadministered with drugs that are strong CYP3A enzyme inducers.
<i>Available as Multi-Tablet Regimen with Twice-Daily Dosing</i>	
TAF 25 mg/FTC or TDF 300 mg/ FTC and RAL (B3) [Descovy or Truvada and Isentress]	<ul style="list-style-type: none"> For TAF/FTC, initiate only in patients with CrCl ≥ 30 mL/min. For TDF/FTC, initiate only in patients with CrCl ≥ 50 mL/min. For TDF/FTC, use with caution in patients with or at risk for osteoporosis. Administer as TAF/FTC or TDF/FTC once daily and RAL 400 mg twice daily. Magnesium- or aluminum-containing antacids are contraindicated; calcium-containing antacids are acceptable with RAL.
TAF 25 mg/FTC or TDF 300 mg/ FTC and RAL HD (A2) [Descovy or Truvada and sIsentress HD]	<ul style="list-style-type: none"> For TAF/FTC, initiate only in patients with CrCl ≥ 30 mL/min. Contains 25 mg of TAF, unboosted. For TDF/FTC, initiate only in patients with CrCl ≥ 50 mL/min. For TDF/FTC, use with caution in patients with or at risk for osteoporosis. Administer as TAF/FTC or TDF/FTC once daily and RAL HD 1,200 mg once daily, dosed as two 600 mg HD tablets. To date, no clinical trials have been conducted with TAF and RAL; data are based on bioequivalence pharmacokinetic studies. Magnesium- or aluminum-containing antacids are contraindicated; coadministration of calcium-containing antacids is not recommended with RAL HD.
<ul style="list-style-type: none"> Additional abbreviations: CrCl, creatinine clearance; CYP, cytochrome P450. ART regimens for individuals of childbearing potential: Refer to DHHS: Recommendations for the Use of Antiretroviral Drugs During Pregnancy 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 ARV Dose Adjustments for Hepatic or Renal Impairment section in full guideline. 	