SELECTING AN INITIAL ART REGIMEN

ALL RECOMMENDATIONS

P.1

- Clinicians should involve their patients when deciding which ART regimen is most likely to result in patient adherence (AII).
- Clinicians should perform the following when initiating ART:
  - Assessment for comorbidities that may affect the choice of regimen for initial therapy (AII).
  - Genotypic resistance testing for the protease and reverse transcriptase genes at diagnosis or at the initial visit if not performed previously (AII). See the section of this guideline, Specific Factors to Consider and Discuss with Patients, for more information.
- Baseline testing is not recommended for either integrase resistance or tropism (AII).
- For patients who have delayed initiation of ART and have engaged in high-risk behaviors associated with acquisition of HIV superinfection, genotypic resistance testing should be repeated before choosing the ART regimen (BIII).
- Clinicians should consult with a care provider experienced in ART management when:
  - Baseline resistance requires treatment with a regimen other than the recommended preferred or alternative regimens (AII).
  - Selecting a regimen for patients with extensive comorbidities (BIII), impaired renal function (BIII), HBV or HCV co-infections (BIII), active opportunistic infections (BIII), or very high viral loads (BIII).

This ¼-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline Selecting an Initial Antiretroviral Therapy (ART) Regimen.

Guideline Contents:
- Available ART Regimens
- General Principles in Choosing an Initial ART Regimen
- General Considerations with Initial ART Regimens
- Specific Factors to Consider and Discuss with Patients
- Special Considerations for Comorbid Conditions
- Pre-ART—Initiation Laboratory Testing
- ARV Dose Adjustments for Renal and Hepatic Impairment

The full guideline is available at www.hivguidelines.org.

HIV CLINICAL RESOURCE

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SELECTING AN INITIAL ART REGIMEN

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE

NOVEMBER 2017 UPDATE

ALL RECOMMENDATIONS

P.1
### ALTERNATIVE Initial ART Regimens for Non-Pregnant Adults

#### Alphabetical list; for details see Specific Factors to Consider or drug package inserts

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>Available as a Single-Tablet Formulation</strong></td>
<td></td>
</tr>
</tbody>
</table>
| TAF 25 mg/FTC/RPV (Odefsey) | - Initiate only in patients with CrCl of ≥30 mL/min.  
- Initiate only in patients with CD4 cell count ≥200 cells/mm³ and viral load <10,000 copies/mL.  
- Use with caution in patients with depression or a history of suicidality.  
- No clinical trials to date; data based on bioequivalence PK studies.  
- Contraindicated with PPIs.  
- Use H₂–blockers with caution and separate dosing by 12 hours.  
- Must take with food.  
- Contains 25 mg of TAF, unboosted.  
| **Available as Multi-Tablet Regimen with Once–Daily Dosing** | |
| TDF/FTC and DRV/COBI (Truvada and Prezincobic) | - Initiate only in patients with CrCl ≥50 mL/min.  
- Carefully consider drug–drug interactions with COBI.  
- Consider bone mineral density.  
| TDF/FTC and DRV and RTV (Truvada and Prezista and Norvir) | - Initiate only in patients with CrCl ≥50 mL/min.  
- Carefully consider drug–drug interactions with DRV and RTV.  
- Consider bone mineral density.  
| TDF/FTC and DTG (Truvada and Tivicay) | - Initiate only in patients with CrCl ≥50 mL/min.  
- No documented DTG resistance after initiation in treatment-naïve patients to date.  
- Consider bone mineral density.  
| TDF/FTC and RAL HD (Truvada and Isentress HD) | - Initiate only in patients with CrCl ≥50 mL/min.  
- Carefully consider drug–drug interactions with RAL.  
- Consider bone mineral density.  
- TDF/FTC once daily and RAL HD 1200 mg once daily dosed as two 600 mg HD tablets.  
| **Available as Multi-Tablet Regimen with Twice–Daily Dosing** | |
| TAF 25 mg/FTC and RAL (Truvada and Isentress) | - Initiate only in patients with CrCl ≥50 mL/min.  
- Carefully consider drug–drug interactions with RAL.  
- Consider bone mineral density.  
- TDF/FTC once daily and RAL twice daily.  |

**Notes:** 1) In all cases, FTC and 3TC are interchangeable when not being used in fixed-dose combinations; 2) Because of their drug–interaction profiles, COBI and RTV should not be considered interchangeable; 3) TAF 10 mg and TAF 25 mg are not interchangeable; 4) Refer to Table 9: ARV Dose Adjustments for Renal and Hepatic Impairment for adjustment based on renal or hepatic function; 5) When dosing RAL once daily use the HD formulation of 600 mg tablets dosed at 1200 mg.

### Food Requirements for Antiretroviral Medications (ARVs)

Because patients may have a strong preference for taking medication with or without food, it is important to discuss which pills must be taken on an empty stomach, which must be taken with food, and which can be taken with or without food, as listed below.

- **ARVs that can be taken WITH OR WITHOUT FOOD**
  - 3TC
  - ABC
  - DTG
  - FTC
  - RAL

- **ARVs that must be taken WITH FOOD**
  - ATV/COBI
  - ATV and RTV
  - DRV/COBI
  - DRV and RTV
  - EVG

**Drug name abbreviations:** abacavir (ABC); atazanavir (ATV); cobicistat (COBI); darunavir (DRV); deguelovir (DTG); efavirenz (EFV); elvitegravir (EVG); emtricitabine (FTC); lamivudine (3TC); raltegravir (RAL); rilpivirine (RPV); ritonavir (RTV); tenofovir alafenamide (TAF); tenofovir disoproxil fumarate (TDF)

### Select Drug–Drug Interactions to Discuss before Initiating ART in Treatment–Naïve Patients

<table>
<thead>
<tr>
<th>Drugs</th>
<th>ARVs(s): Comments</th>
</tr>
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</table>
| H₂–blockers, antacids | ATV: In treatment–naïve patients on boosted ATV, H₂–blockers should be either 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 one dose and no more than 40 mg twice daily of famotidine or equivalent for daily dose.  
RPV: Use with caution; administer at least 12 hours before or at least 4 hours after RPV.  
| Inhaled steroids, statins | COBI; RTV: Alternatives or dose adjustments may be needed.  
PPIs | 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.  
EVG: Separate dosing by 2 hours, either before or after dose of EVG.  
| Polynuclear cations [a] | 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 aluminium–containing antacids are contraindicated; calcium–containing antacids are acceptable.  
EVG: Separate dosing by 2 hours, either before or after dose of EVG.  
| Ethyl alcohol | EFV; COBI/ATV; COBI/DRV; RTV and DRV: Use alternative or additional (e.g., barrier) contraceptive methods or choose alternative ART regimen.  
ATV; RTV and ATV: 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).  
- 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.  
| Drug name abbreviations:** atazanavir (ATV); cobicistat (COBI); darunavir (DRV); deguelovir (DTG); efavirenz (EFV); elvitegravir (EVG); emtricitabine (FTC); lamivudine (3TC); raltegravir (RAL); rilpivirine (RPV); ritonavir (RTV)  
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 package insert for specific ARV for dosing instructions and safety information.  

### CONTRAINDICATED ART Regimens Based on Routine Baseline* Laboratory Parameters

<table>
<thead>
<tr>
<th>Lab Parameter</th>
<th>Contraindicated ART Regimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load ≥100,000 copies/mL</td>
<td>ABC/3TC and COBI/ATV, ABC/3TC and EFV, ABC/3TC and RTV and ATV and DRV, TDF/FTC/RPV, TDF/FTC/RPV</td>
</tr>
<tr>
<td>CD4 &lt;200 cells/mm³</td>
<td>TAF/FTC/RPV, TDF/FTC/RPV</td>
</tr>
<tr>
<td>CrCl ≥70 mL/min</td>
<td>TDF/FTC and COBI/ATV, TDF/FTC and COBI/DRV, TDF/FTC/COBI/EVG</td>
</tr>
<tr>
<td>CrCl &lt;50 mL/min</td>
<td>ABC/3TC, ABC/3TC/DTG, TDF/FTC/EVF, TDF/FTC/RPV</td>
</tr>
<tr>
<td>CrCl &lt;30 mL/min</td>
<td>TAF/FTC, TAF/FTC/COBI/EVG, TAF/FTC/RPV, TDF/FTC</td>
</tr>
</tbody>
</table>

**Drug name abbreviations:** abacavir (ABC); atazanavir (ATV); cobicistat (COBI); darunavir (DRV); deguelovir (DTG); efavirenz (EFV); elvitegravir (EVG); emtricitabine (FTC); lamivudine (3TC); raltegravir (RAL); rilpivirine (RPV); ritonavir (RTV); tenofovir alafenamide (TAF); tenofovir disoproxil fumarate (TDF)  
* For renal adjustment of FDCs and single-tablet regimens while on therapy, see Table 8 in the full guideline.