

HIV/AIDS Quick Sheet

DEFINITIONS		
ART = antiretroviral therapy	NRTI = nucleoside reverse transcriptase inhibitor	
CrCl = creatinine clearance	NNRTI = non-nucleoside reverse transcriptase inhibitor	
INSTI = Integrase Strand Transfer Inhibitor	PI = protease inhibitor	
ANTIRETROVIRAL ABBREVIATIONS		
ABC = Abacavir	DTG = Dolutegravir	NVP = Nevirapine
ATV/cobi = Atazanavir/cobicistat	EFV = Efavirenz	RAL = Raltegravir
ATV/r = Atazanavir/ritonavir	ETR = Etravirine	RPV = Rilpivirine
cobi = Cobicistat	EVG = Elvitegravir	RTV = ritonavir
d4T = Stavudine	FTC = Emtricitabine	SQV = Saquinavir
ddC = Zalcitabine	3TC = Lamivudine	T20 = Fuzeon
ddI = Didanosine	FPV = fosamprenavir calcium	TDF = Tenofovir disoproxil fumarate
DRV/cobi = Darunavir/cobicistat	IDV: Indinavir	TPV = Tipranavir
DRV/r = Darunavir/ritonavir	LPV/r = Lopinavir/ritonavir	ZDV = Zidovudine

Initiating Antiretroviral (ARV) Therapy in Treatment-Naive Patients

Optimal ARV regimen consists of two NRTIs in combination with a 3rd active ARV drug from 1 of 3 drug classes:

- (2) NRTI's + **INSTI**
- (2) NRTI's + **boosted PI (boosted with Ritonavir or Cobicistat)**
- (2) NRTI's + **NNRTI**

ANTIRETROVIRAL (ARV) REGIMENS FOR ART-NAÏVE PATIENTS		
Recommended Regimen Options		
INSTI Based		
• DTG + ABC**/3TC*	Triumeq™	• DTG + TAF/FTC* or TDF/FTC*
• EVG/cobi***/TAF/FTC	Genvoya™	• RAL#### + TDF/FTC* or TAF/FTC*
• EVG/cobi***/TDF/FTC	Stribild™	• BIC (Bictegravir)/TAF/FTC Biktarvy™
Recommended Initial Regimens in Certain Clinical Situations		
<i>Effective and tolerable but have some disadvantages when compared with the above recommended regimens, or have less supporting data from randomized clinical trials. However, one of the following regimens may be the preferred regimens in certain clinical situations.</i>		
PI Based [¥]	NNRTI Based	
• (DRV/cobi*** or DRV/r) + TAF/FTC* or TDF/FTC*	• EFV + TDF/FTC*	Atripla™
• (DRV/cobi*** or DRV/r) + ABC**/3TC*	• EFV + TAF/FTC*	
• (ATV/cobi*** or ATV/r) + TAF/FTC* or TDF/FTC*	• RPV [#] + TDF/FTC*	Complera™
• (ATV/cobi*** or ATV/r) + ABC**/3TC* (##)	• RPV [#] + TAF/FTC*	Odefsey™
INSTI Based	If TDF, TAF or ABC cannot be used	
• RAL#### + ABC**/3TC* (##)	• DRV/r + RAL (twice daily) [#]	
	• LPV/r ^{¥¥} (twice daily) + 3TC* (twice daily)	
* 3TC may be substituted for FTC or vice versa	** Use ABC only for HLA-B*5701 negative patients	
*** Use Genvoya™ only with pre-ART CrCl ≥ 30 mL/min	*** Use coBI/TDF only with pre-ART CrCl ≥ 70 mL/min	
# Use regimen only for patients with pre-treatment HIV RNA < 100,000 copies/mL and CD4 cell count >200 cells/mm ³		
## regimen only for patients with pre-treatment HIV RNA < 100,000 copies/mL		
### RAL can be given as 400 mg BID or 1200 mg (two 600-mg tablets) once daily		
¥ In general, boosted DRV is preferred over boosted ATV		
¥¥ published 48-week data in a randomized controlled trial in ART-naive patients. Limitations of LPV/r plus 3TC include twice-daily dosing, high pill burden, and greater rates of gastrointestinal side effects than other PIs		
Other co-formulations: (TAF: Tenofovir Alafenamide)		
ABC/3TC: Epzicom™	TAF/FTC: Odefsey™	TDF/FTC: Truvada™
DRV/cobi: PrezcoBix™	ATV/cobi: Evotaz™	

Antiretroviral Regimens or Components That Should Not Be Offered At Any Time

Not generally recommended due to suboptimal antiviral potency, unacceptable toxicities, or pharmacologic concerns

Monotherapy with NRTI, NNRTI, entry inhibitor, PI or INSTI	ATV + IDV
Dual-NRTI or NNRTI or Triple-NRTI regimens	ddl + d4T
EFV in 1st trimester or with significant child-bearing potential	ddl + TDF
NVP in pre-ARV CD4 > 250 in women or > 400 in men	d4T + ZDV
Unboosted DRV, SQV or TPV	FTC+ 3TC
Unboosted RTV doses (e.g., 600mg BID)	TDF + TAF
Cobicistat + Ritonavir	ETR + TPV/r or ARV/r or FPV/r or unboosted PI

Selection of a regimen should be individualized based on virologic efficacy, toxicity, pill burden, dosing frequency, drug-drug interaction potential, resistance testing results, comorbid conditions, and cost. Dose adjustments in renal and hepatic insufficiency can be found at; <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/44/arv-dosing-for-renal-or-hepatic-insufficiency>

Do not dispense partial regimens. The patient must have all prescribed medications; otherwise they are at risk for developing medication resistance (and potential class-cross resistance) from taking a partial regimen. Counsel patients to take prescribed medications the same time daily, and avoid gaps in treatment.

A specialist in HIV should be consulted if questions arise concerning an individual's HIV regimen.

Reference: <http://aidsinfo.nih.gov/guidelines>

Recommendations for Use of Antiretroviral Drugs during Pregnancy

	NRTIs	NNRTIs	PIs	Entry Inhibitors	Integrase Inhibitors
Preferred	ABC*/ 3TC TDF/ (3TC or FTC)		ATV/r DRV/r (twice daily)		RAL (twice daily)
Alternate	ZDV/ 3TC	RPV EFV***	LPV/r (twice daily)		DTG
Insufficient Data	TAF/FTC	Odefsey™			
Not Recommended	ABC*/3TC/ZDV ddl + d4T [#] ddC	NVP** ETR	FPV SQV/r IDV/r TPV/r NFV RTV (as single PI)	T20 MVC	Prezcobix™ Stribild™ Genvoya™ Cobicistat
* Use ABC only for HLA-B*5701 negative patients			** Use with caution: use only if CD4 count < 250		
*** anencephaly, microphthalmia, cleft palate					
[#] Implicated in death of a client: severe lactic acidosis with hepatic steatosis with or without pancreatitis					

ATV/r: Use of an increased dose (400 mg ATV plus 100 mg RTV once daily with food) during the second and third trimesters results in plasma concentrations equivalent to those in non-pregnant adults on standard dosing. Although some experts recommend increased ATV dosing in all women during the second and third trimesters, the package insert recommends increased ATV dosing only for ARV-experienced pregnant women in the second and third trimesters also receiving either TDF or an H₂-receptor antagonist. There is insufficient data and no PK studies in pregnancy to make dosing recommendations for ATV/cobi (Evotaz™).

DRV/r: Once-daily dosing with DRV/r is not recommended during pregnancy. Twice-daily DRV/RTV dosing (DRV 600 mg plus RTV 100 mg with food) is recommended for all pregnant women. Increased twice-daily DRV dose (DRV 800 mg plus RTV 100 mg with food) during pregnancy does not result in an increase in darunavir exposure and is not recommended. DRV/cobi co-formulation is not recommended for use in pregnancy due to lack of available pregnancy or PK/safety data.

RAL: PK data available with decreased levels in third trimester not of sufficient magnitude to warrant change in dosing. Rapid viral load reduction, thus potential role for women who present for initial therapy late in pregnancy. Useful when drug interactions with PI regimens are a concern. Twice-daily dosing required (400 mg twice daily).

DTG: May 30, 2018. A NIH-funded observational surveillance study of birth outcomes among pregnant women on antiretroviral therapy in Botswana identified neural tube defects in 4 infants born to 426 women who initiated a DTG-based regimen prior to pregnancy, and who were still receiving it at the time of conception. The DHHS Antiretroviral Guidelines Panels have issued recommendations for treatment of adults and adolescents with HIV who are pregnant or of child-bearing potential. <https://aidsinfo.nih.gov/news/2109/recommendations-regarding-the-use-of-dolutegravir-in-adults-and-adolescents-with-hiv-who-are-pregnant-or-of-child-bearing-potential>

LPV/r: Once daily dosing is not recommended during pregnancy. Some experts recommend that an increased dose, from LPV 400 mg + RTV 100 mg twice daily to LPV 600 mg + RTV 150 mg twice daily without regard to meals, should be used in the 2nd and 3rd trimesters, especially in PI- experienced pregnant women and women who start treatment during pregnancy with a baseline viral load >50 copies/mL. If standard dosing is used, monitor virologic response and LPV drug levels, if available.

EFV: Concern due to birth defects seen in primate studies, but data not borne out in human studies and extensive experience in pregnancy; cautionary text remains in package insert. Consider in women who require co-administration of drugs with significant interactions with preferred agents, or who need the convenience of a co-formulated, single-tablet, once-daily regimen and are not eligible for RPV. Screening for antenatal and postpartum depression is recommended. Higher rate of adverse events than drugs in Preferred category.

RPV: Not recommended with pretreatment HIV RNA >100,000 copies/mL or CD4 cell count <200 cells/mm³. Do not use with PPIs. PK data available in pregnancy but relatively little experience with use in pregnancy. Available in coformulated single-pill, once-daily regimen.

TDF/FTC: A recent [BMJ](#) clinical practice guideline recommended that pregnant women living with HIV should not be treated with the combination of TDF/FTC. After fully considering the results of the [PROMISE study](#), both the Panel and the [British HIV Association](#) do not support these recommendations. The Panel found that there were important study design and statistical considerations that limit the generalizability of the PROMISE findings, and in consideration of all available evidence, the Panel concluded that the assessment of expected benefits and harms favored TDF/FTC over ZDV/3TC, leading the Panel to keep TDF/FTC as a Preferred recommendation and ZDV/3TC as an Alternative recommendation for antiretroviral-naïve pregnant women living with HIV in the United States.

Food Requirements	With or Without Food	With Food	Empty Stomach
NRTI	ABC, FTC, d4T, TDF, AZT	3TC	ddI
NNRTI	DLV, NVP	ETR ^{##} , RPV [¥]	EFV
PI	FPV*, LPV/r**, TPV/r [¶]	ATV ^{¥¥} , DRV/r, NFV [‡] , RTV, IDV ^{‡‡} , SQV/r ^{€€} , TPV/r ^{¶¶}	
Entry Inhibitor	T-20, MVC		
INSTI	DTG, RAL [#]	EVG [€]	
PK Enhancer		Cobi	
Combination therapy	Combivir [™] , Biktarvy [™] Descovy [™] , Epzicom [™] , Truvada [™] Triumeq [™] , Trizivir [™]	Stribild [™] , Genvoya [™] , Complera [™] ¥, Odefsey [™] , Prezcobix [™] , Evotaz [™]	Atripla [™]

* Adults: oral suspension without food. Children: oral suspension with food

** Oral solution with food

Chewable tablets may be chewed or swallowed

Always after a meal. Can dissolve tablets in a small amount of water

¥ Always with at least a 400-calorie meal. A protein drink alone does not replace a meal.

¥¥ Do not open the capsules

‡ Can dissolve tablets or powder in a small amount of water

‡‡ Take with water at least 1 hour before or 2 hours after a meal Or with a light meal that is low in calories, fat, and protein

€ Oral suspension must be mixed with water before use and given within 30 minutes of mixing

€€ Take with full meal or up to 2 hours after a meal. Capsules can be opened & contents mixed with 15 mL of sugar, syrup or jam

¶ Capsules or oral solution, taken with or without meals

¶¶ Tablets, take only with meals

Alternative Formulations	Liquid	Chewable	Powder
NRTI	ABC, ddI, FTC, 3TC, d4T, ZDV		TDF
NNRTI	NVP		
PI	DRV, FPV, LPV/r, RTV, TPV		ATV, NFV, RTV
INSTI	RAL	RAL	

Refer to the most up to date package insert for dosing requirements

Pregnancy/Newborn Highlights

Georgia Law: § 31-17-4.2. HIV and Syphilis Pregnancy Screening

Every healthcare provider who assumes responsibility of care... shall be required to test for HIV & syphilis except in cases where the woman refuses. Additionally... during the 3rd trimester shall offer HIV & syphilis tests at the time of 1st exam regardless of whether testing was performed during the first 2 trimesters.

Therapy of HIV positive woman:

ART is currently recommended for all HIV-infected individuals to reduce the risk of disease progression and to prevent HIV sexual transmission. Women should continue their antepartum combination ART drug regimen on schedule as much as possible during labor and before scheduled cesarean delivery.

IV ZDV at delivery:

Administer IV ZDV to HIV-infected women with HIV RNA >1,000 copies/mL, or unknown HIV RNA, near delivery, but is not required for HIV-infected women receiving ART regimens who have HIV RNA ≤1,000 copies/mL during late pregnancy and near delivery and no concerns regarding ART adherence.

C-Section:

Scheduled cesarean delivery at 38 weeks' gestation, compared to 39 weeks for most indications, is recommended for women who have HIV RNA >1,000 copies/mL near delivery.

In women on ART with HIV RNA ≤1,000 copies/ml, duration of ruptured membranes is not associated with an increased risk of perinatal transmission, and vaginal delivery is recommended.

Breastfeeding and Premastication:

Health care providers should routinely inquire about breastfeeding and premastication; instruct HIV-infected caregivers to avoid these practices, and advise on safer feeding options.

Newborn testing:

Virologic tests are required to diagnose HIV infection in infants aged <18 months and should be performed at 14 to 21 days of life and at ages 1 to 2 months and 4 to 6 months.

Newborn care:

All HI-exposed infants should receive postpartum ARV drugs to reduce the risk of perinatal transmission of HIV and be initiated as close to the time of birth as possible, preferably within 6 -12 hours of delivery.

A 4-week neonatal ZDV prophylaxis regimen can be used for full-term infants when the mother has received standard ART during pregnancy with sustained viral suppression and there are no concerns related to maternal adherence. Otherwise, a 6-week prophylaxis regimen is recommended.

Combination prophylaxis regimen is recommended in infants at higher risk of HIV acquisition, including those born to HIV-infected women who:

- Have not received antepartum or intrapartum ARV drugs, *or*
- Have received only intrapartum ARV drugs, *or*
- Have received antepartum ARV drugs but do not have viral suppression near delivery

All infants born to HIV-infected women should begin PCP prophylaxis at ages 4-6 weeks, after completing ARV prophylaxis regimen, unless adequate test information presumptively excludes HIV infection.

Hot-lines: <http://nccc.ucsf.edu/> Reference: <https://aidsinfo.nih.gov/guidelines/html/3/perinatal/0>
www.gacapus.com

REMINDERS

- ❖ Regimens should include at least (3) fully active medications
- ❖ Check for “incomplete” regimens; NEVER dispense partial regimens
- ❖ Counsel patients to take all regimen components to reduce risk of developing medication resistance



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