Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (page 1 of 4)

Note: For information about specific ARV drugs and dosing in pregnancy, see Table 6, Table 10, and the individual drug sections in Appendix B.

ART Regimen Component **Note:** ARV drugs and ARV regimens are listed alphabetically within drug classes and recommendation categories	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on an ART Regimen that has been Well Tolerated and Virologically Suppressive[a]	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[b]	New ART Regimen for Pregnant Women Whose Current ART is not Well Tolerated and/or is not Resulting in Virologic Suppression[b]	ART for Nonpregnant Women Who Are Trying to Conceive[b,c]
NRTIs[d,e]					
ABC	Preferred	Continue	Preferred	Preferred	Preferred
FTC	Preferred	Continue	Preferred	Preferred	Preferred
3TC	Preferred	Continue	Preferred	Preferred	Preferred
TDF	Preferred	Continue	Preferred	Preferred	Preferred
ZDV	Alternative	Continue	Alternative	Alternative	Alternative
TAF	Insufficient data[f]	Continue	Insufficient data	Insufficient data	Insufficient data
INSTIs Used in combination with a dual-NRTI backbone[e]					
DTG These are interim recommendations, pending the availability of additional data.[g]	Not recommended during the first trimester[g] Preferred after the first trimester	Consider continuation with counseling or switch during the first trimester[g] Continue if patient is in the second or third trimester	Not recommended during the first trimester[g] Preferred after the first trimester	Not recommended during the first trimester[g] Preferred after the first trimester	Not recommended[g]
RAL	Preferred	Continue	Preferred	Preferred	Preferred
BIC	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
EVG/COBI	Not recommended[h]	Consider switch, or continue with frequent viral load monitoring[h]	Not recommended[h]	Not recommended[h]	Not recommended[h]
PIs Used in combination with a dual-NRTI backbone[e]					
ATV/r	Preferred	Continue	Preferred	Preferred	Preferred
DRV/r	Preferred	Continue	Preferred	Preferred	Preferred
LPV/r	Alternative	Continue	Alternative	Alternative	Alternative
ATV/COBI	Not recommended[h]	Consider altering the regimen, or continuing the same regimen with frequent viral load monitoring[h]	Not recommended[h]	Not recommended[h]	Not recommended[h]
DRV/COBI	Not recommended[h]	Consider altering the regimen, or continuing the same regimen with frequent viral load monitoring[h]	Not recommended[h]	Not recommended[h]	Not recommended[h]

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (page 2 of 4)

ART Regimen Component **Note:** ARV drugs and ARV regimens are listed alphabetically within drug classes and recommendation categories	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on an ART Regimen that has been Well Tolerated and Virologically Suppressive[a]	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[b]	New ART Regimen for Pregnant Women Whose Current ART is not Well Tolerated and/or is not Resulting in Virologic Suppression[b]	ART for Nonpregnant Women Who Are Trying to Conceive[b,c]
NNRTIs Used in combination with a dual-NRTI backbone[e]					
EFV	Alternative	Continue	Alternative	Alternative	Alternative
RPV[i]	Alternative[i]	Continue[i]	Alternative[i]	Alternative[i]	Alternative[i]
DOR	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
ETR	Not recommended	Continue	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]
NVP	Not recommended	Continue	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]
Entry and Fusion Inhibitors					
IBA	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
MVC	Not recommended	Continue	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]
T-20	Not recommended	Continue	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]	Not recommended, except in special circumstances[j]
FDC Regimens[e] The individual drug component that is most responsible for the overall recommendation is indicated in parentheses.					
ABC/DTG/3TC[g]	Not recommended during the first trimester Preferred after the first trimester (DTG[g])	Consider continuation with counseling or switch during the first trimester Continue if patient is in the second or third trimester (DTG[g])	Not recommended during the first trimester Preferred after the first trimester (DTG[g])	Not recommended during the first trimester Preferred after the first trimester (DTG[g])	Not recommended (DTG[g])
EFV/FTC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
EFV/3TC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
FTC/RPV/TDF	Alternative (RPV[i])	Continue (RPV[i])	Alternative (RPV[i])	Alternative (RPV[i])	Alternative (RPV[i])
BIC/FTC/TAF	Insufficient data (BIC, TAF)	Insufficient data (BIC)	Insufficient data (BIC, TAF)	Insufficient data (BIC, TAF)	Insufficient data (BIC, TAF)

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (page 3 of 4)

ART Regimen Component **Note:** ARV drugs and ARV regimens are listed alphabetically within drug classes and recommendation categories	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on an ART Regimen that has been Well Tolerated and Virologically Suppressive[a]	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[b]	New ART Regimen for Pregnant Women Whose Current ART is not Well Tolerated and/or is not Resulting in Virologic Suppression[b]	ART for Nonpregnant Women Who Are Trying to Conceive[b,c]
DOR/3TC/TDF	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)
FTC/RPV/TAF	Insufficient data (TAF[f])	Continue (RPV[i], TAF[f])	Insufficient data (TAF[f])	Insufficient data (TAF[f])	Insufficient data (TAF[f])
EVG/COBI/FTC/TDF	Not recommended (EVG/COBI[h])	Consider switch or continue with frequent viral load monitoring (EVG/COBI[h])	Not recommended (EVG/COBI[h])	Not recommended (EVG/COBI[h])	Not recommended (EVG/COBI[h])
EVG/COBI/FTC/TAF	Not recommended[h] (EVG/COBI[h])	Consider switch or continue with frequent viral load monitoring (EVG/COBI[h])	Not recommended (EVG/COBI[h])	Not recommended (EVG/COBI[h])	Not recommended (EVG/COBI[h])
DRV/COBI/FTC/TAF	Not recommended (DRV/COBI[h])	Consider switch or continue with frequent viral load monitoring (DRV/COBI[h])	Not recommended (DRV/COBI[h])	Not recommended (DRV/COBI[h])	Not recommended (DRV/COBI[h])
DTG/RPV As a complete regimen[k]	Not recommended[g,k]	Not recommended during the first trimester (DTG,[g] RPV[k]) If after the first trimester, switch or add additional agents (DTG[g]/RPV[k])	Not recommended[g,k]	Not recommended[g,k]	Not recommended[g,k]

[a] When changes in ARV regimens are being considered, women should be given information about the benefits and risks of switching ARV drugs so they can participate in decision making.

[b] **Do not initiate** ARV regimens with component that have documented resistance or suspected resistance based on prior ARV exposure.

[c] This guidance is intended for women who are trying to conceive. These recommendations are not intended for all women living with HIV who might become pregnant.

[d] ABC/3TC, TDF/FTC, and TDF/3TC are preferred two-NRTI backbones and ZDV/3TC is an alternative two-NRTI backbone for ART regimens.

[e] When using FDCs, refer to Table 10 and the drug sections in Appendix B for information about the dosing and safety of individual components of the FDC during pregnancy.

[f] Available data about the use of TAF in pregnancy support continuing it in pregnant women who are virally suppressed, although data are insufficient to recommend it when initiating ART in pregnancy.

[g] The following are interim recommendations pending additional data: DTG is a preferred INSTI for pregnant women after the first trimester, based on available PK, safety, and efficacy data. However, because of concerns about congenital anomalies that may have occurred both during and after neural tube closure (which occurs around 4 weeks post-conception and 6 weeks after the last menstrual period), the Panel **does not recommend** the use of DTG during the first trimester. The first trimester is less than 14 weeks (up to 13 6/7 weeks) gestational age by last menstrual period. This is intended to be a conservative, interim recommendation and will be revised, if indicated, as additional data become available in 2019. Although DTG is not FDA-approved for use in the first trimester, some Panel members would consider using DTG at 12 weeks gestational age by last menstrual period on an individual patient basis. For women who become pregnant while taking DTG and who present to care during the first trimester, providers should counsel patients about the risk of neural tube defects and the risk of viral rebound (with associated risk for perinatal transmission) if changes are made to the ART regimen. For more information, see Interim Panel Recommendations Regarding the Use of Dolutegravir at the Time of Conception in Preconception Counseling and Care and Interim Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy in Recommendations for the Use of Antiretroviral Drugs During Pregnancy.

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[h] DRV/COBI, EVG/COBI, and ATV/COBI **are not recommended** for use in pregnancy due to PK changes that pose a risk for low drug levels and viral rebound in the second and third trimesters. However, in pregnant women who present as virologically suppressed on these regimens, it is appropriate to consider continuing them with increased viral load monitoring. If there are concerns about switching, see Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy. Although PK data on ATV/COBI are not available yet, it is anticipated that the data will show pharmacokinetic changes that are similar to those observed with DRV/COBI and EVG/COBI.

[i] Although PK data indicate that RPV plasma concentration is reduced during the second and third trimester, the reduction is less than the reductions seen with EVG/COBI or DRV/COBI. Higher-than-standard doses have not been studied, so there are insufficient data to recommend a dose change in pregnancy. With standard dosing, viral load should be monitored more frequently.

[j] Although these drugs are not recommended for initial treatment in ART-naive pregnant women, there may be special circumstances in which treatment-experienced women may need to continue or initiate ETR, NVP, MVC, and T-20 in order to maintain or achieve viral suppression. There are limited safety and efficacy data about the use of ETR, MVC, and T-20 in pregnancy. NVP is not recommended for ART-naive women because it has a greater potential for adverse events than other NNRTIs, complex lead-in dosing, and low barrier to resistance; however, if a pregnant woman presents to care on a well-tolerated, NVP-containing regimen, it is likely that NVP will be safe and effective during pregnancy. See Table 6 and Nevirapine for more information.

[k] 2-drug ART regimens **are not recommended** for use in pregnancy.

The following drugs (that are not listed above) should not be used in pregnancy; if a woman becomes pregnant while taking these medications, she should switch to a recommended regimen: d4T, ddI, FPV, FPV/r, IDV, IDV/r, NFV, RTV (as a sole PI), SQV, SQV/r, TPV, TPV/r, or a three-NRTI ART regimen (e.g., ABC/ZDV/3TC). See Table 10 and What Not to Use in the Adult and Adolescent Antiretroviral Guidelines for additional information about ARV drugs and ARV combinations that are not recommended for use in adults and refer to the table above and Table 6 for ARV regimens that are recommended for use in pregnancy.

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/r = atazanavir/ritonavir; BIC = bictegravir; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV = darunavir; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FDA = Food and Drug Administration; FDC = fixed-dose combination; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; IBA =ibalizumab; IDV = indinavir; IDV/r = indinavir/ritonavir; INSTI = integrase strand transfer inhibitor; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQV = saquinavir; SQV/r = saquinavir/ritonavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumerate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; ZDV = zidovudine