Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive

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Recommendations for initial antiretroviral therapy (ART) during pregnancy are intended for people **who have never received ART or antiretroviral (ARV) drugs for prophylaxis** (i.e., people who are ARV-naive) and show no evidence of significant resistance to regimen components (see Pregnant People with HIV Who Have Never Received Antiretroviral Drugs [Antiretroviral-Naive]). Recommendations about the use of ARVs in other scenarios are detailed in Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive.

In general, the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) recommends that people **who are already on fully suppressive ARV regimens when pregnancy occurs should continue with those regimens,** unless they are receiving an ARV drug or ARV regimen that is not recommended for use in nonpregnant adults or concerns exist about safety and inferior efficacy during pregnancy (see Table 7 and People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant). Clinicians may need to consider additional factors when initiating ART in patients who previously received ART or ARV drugs for prophylaxis (see Pregnant People with HIV Who Have Previously Received Antiretroviral Medications but Are Not Currently on Antiretroviral Medications and Table 7).

Whenever possible, changes in ARV regimens should be timed so that individuals are able to achieve viral suppression before they begin trying to become pregnant (see Table 7).

Regimens are listed alphabetically within each drug class and recommendation category for initial therapy in people who are ARV-naive, so the order does not indicate a ranking of preference. In addition, except where noted below, the Panel makes no recommendation for one agent or regimen over another within each category (e.g., among *Preferred* or *Alternative* medications). The table also indicates ARV drugs or regimens that are available in fixed-dose combination tablets. Patients and providers should make shared decisions about which ARV drugs to use during pregnancy after discussing the benefits of ART and the known and potential risks to pregnant people and their fetuses (see Appendix C: Antiretroviral Counseling Guide for Health Care Providers and Recommendations for Use of Antiretroviral Drugs During Pregnancy: Overview).

Note: For more information about the use of specific drugs and dosing in pregnancy, see Table 7, the individual drug sections in Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy, and Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy.

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Preferred Initial Regimens in Pregnancy		
Drugs or drug combinations are designated as *Preferred* for therapy during pregnancy when clinical trial data in adults have demonstrated efficacy and durability with acceptable toxicity and ease of use, and pregnancy-specific PK data are available to guide dosing. In addition, the available data must suggest a favorable risk-benefit balance for the drug or drug combination compared with other ARV drug options; the assessment of risks and benefits should incorporate outcomes for the health of the pregnant person, fetus, and infant. Some *Preferred* drugs or regimens may have minimal toxicity or teratogenicity risks that are offset by other advantages for people with HIV who are pregnant or who are trying to conceive. Therefore, it is important to read all the information on each drug in the Perinatal Guidelines before administering any of these medications to patients (see Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy).		
Preferred Dual-NRTI Backbones	Advantages	Disadvantages
ABC/3TC	• Once-daily dosing • Available as an FDC • Well-tolerated during pregnancy • Reassuring PK data during pregnancy	• Requires HLA-B*5701 testing before use. ABC **should not be used** in patients who test positive for HLA-B*5701 because of the risk of developing a hypersensitivity reaction. Requires education about hypersensitivity reactions. • ABC is not active against HBV; see Hepatitis B Virus/HIV Coinfection for recommended dual NRTI backbones. • ABC/3TC administered with ATV/r or EFV is not recommended if pre-treatment HIV RNA is >100,000 copies/mL. • ABC is not recommended as part of regimens for initial treatment of acute HIV infection unless the patient previously tested negative for the HLA-B*5701 gene variant; using TDF or TAF rather than ABC will avoid delays in ART initiation while awaiting HLA-B*5701 test results.
TAF/FTC *or* TAF plus 3TC	• Once-daily dosing • Available as an FDC • Reassuring PK data and extensive use during pregnancy; no dose adjustment required in pregnancy • Both NRTI combinations active against HBV • Minimal toxicity compared with ZDV/3TC • When combined with DTG, the efficacy and toxicity of TAF/FTC and TDF/FTC for treatment of pregnant patients are similar, but TAF/FTC is associated with fewer adverse birth outcomes and less risk of insufficient weight gain in pregnancy.	• When combined with DTG, TAF/FTC is associated with more treatment-emergent obesity in nonpregnant adult women compared to TDF/FTC. (Notably, the impact on weight gain in pregnancy may be beneficial, as noted in the Advantages column.)

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TDF/FTC *or* TDF/3TC	• Once-daily dosing • Available as an FDC • Reassuring PK data and extensive use during pregnancy; no dose adjustment required in pregnancy • Both NRTI combinations active against HBV • When combined with DTG, the efficacy and toxicity of TAF/FTC and TDF/FTC for treatment of pregnant patients are similar.	• Potential concerns about fetal bone and early-life growth abnormalities exist with TDF, although clinical findings are reassuring to date. • TDF has potential renal toxicity; thus, TDF-based, dual-NRTI combinations should be used with caution in patients with renal insufficiency.
Preferred INSTI Regimens	Advantages	Disadvantages
DTG/ABC/3TC (FDC) *or* DTG plus a *Preferred* Dual-NRTI Backbone	• Once-daily dosing • DTG/ABC/3TC is available as an FDC. • Sufficient data about PK, efficacy, and safety of DTG in pregnancy • High rates of viral suppression • Dose adjustments during pregnancy are not needed. • May be particularly useful when drug interactions or the potential for preterm delivery with a PI-based regimen are a concern. • DTG has been shown to rapidly decrease viral load in ARV-naive pregnant women who present to care later in pregnancy. In nonpregnant adults, DTG is associated with lower rates of INSTI resistance than RAL, and DTG allows for once-daily dosing; for these reasons, DTG is particularly useful for pregnant people presenting late in pregnancy. • DTG with a NRTI backbone of TAF or TDF with 3TC or FTC is the *Preferred* regimen for initial treatment in people with early (acute or recent) HIV infection in people without a history of CAB exposure for PrEP; see Early (Acute or Recent) HIV Infection.	• Potential concerns about excess weight gain with DTG • DTG/ABC/3TC requires HLA-B*5701 testing before use (see ABC/3TC above). • Specific timing and/or fasting recommendations apply if DTG is taken with calcium or iron (e.g., in prenatal vitamins; see Table 14). • DTG is not *Preferred* for initial treatment in people with early (acute or recent) HIV infection *and* a history of CAB exposure for PrEP due to concerns about INSTI resistance mutations; DRV/r is *Preferred* in this situation.

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Preferred PI Regimens	Advantages	Disadvantages
DRV/r plus a *Preferred* Dual-NRTI Backbone	• DRV/r is a *Preferred* PI for initial therapy only in certain circumstances (e.g., exposure to CAB-LA). See DRV/r under *Alternative* PI Regimens below for full details.	• See DRV/r under *Alternative* PI Regimens below.

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Alternative Initial Regimens in Pregnancy		
Drugs or drug combinations are designated as *Alternative* options for therapy during pregnancy when clinical trial data in adults show efficacy and the data in pregnant individuals are generally favorable but limited. Most *Alternative* drugs or regimens are associated with more PK, dosing, tolerability, formulation, administration, or interaction concerns than those in the *Preferred* category, but they are acceptable for use in pregnancy. Some *Alternative* drugs or regimens may have known toxicity or teratogenicity risks that are offset by other advantages for people with HIV who are pregnant or who are trying to conceive. Therefore, it is important to read all the information on each drug in the Perinatal Guidelines before administering any of these medications to patients (see Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy).		
Alternative INSTI Regimens	Advantages	Disadvantages
BIC/TAF/FTC (FDC)	• Coformulated as a single, once-daily pill • High barrier to resistance • No food requirement • No dose adjustment required in pregnancy • No safety concerns observed • High rates of viral suppression	• PK and safety data in pregnancy remain limited to small studies. Drug levels are lower in a pregnant person who is in the second and third trimester than in nonpregnant or postpartum patients and are reduced in later pregnancy to a greater degree for BIC than for DTG. BIC levels remained above the EC_{95} during pregnancy and therefore are anticipated to suppress viral load. • May be associated with weight gain • Specific timing and/or fasting recommendations apply if BIC is taken with calcium or iron (e.g., in prenatal vitamins; see Table 14 and Bictegravir for details).
RAL plus a *Preferred* Dual-NRTI Backbone	• No safety concerns observed. Like DTG, RAL may be particularly useful when drug interactions or the potential for preterm delivery with PI-based regimens are a concern. • PK data are available for RAL in pregnancy when using the twice-daily formulation (400 mg twice daily). • Like DTG, RAL has been shown to rapidly decrease viral load in ARV-naive pregnant women who present to care later in pregnancy. In nonpregnant adults, DTG is associated with lower rates of INSTI resistance than RAL, and DTG permits once-daily dosing; for these reasons, DTG is *Preferred* and RAL is *Alternative* for use during pregnancy.	• Twice-daily dosing in pregnancy is recommended due to low drug level with once-daily dosing during pregnancy. • Not available as an FDC • Lower barrier to resistance than DTG; for this reason, RAL is *Alternative* for use during pregnancy • PK data are not available for the once-daily 1,200 mg (2 × 600 mg) extended-release formulation (raltegravir HD) in pregnancy. • Specific timing and/or fasting recommendations apply if RAL is taken with calcium or iron (e.g., in prenatal vitamins; see Table 14 and Raltegravir for details).

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Alternative PI Regimens	Advantages	Disadvantages
ATV/r plus a *Preferred* Dual-NRTI Backbone	• Once-daily dosing • Extensive experience during pregnancy	• Not available as an FDC • Associated with increased maternal indirect bilirubin levels, which theoretically may increase the risk of neonatal hyperbilirubinemia. No clinically significant neonatal hyperbilirubinemia or kernicterus reported, but neonatal bilirubin monitoring is recommended. • Requires increased dosing in the second or third trimester • Has been associated with small but significant reductions in language and social-emotional scores and late language • PIs may increase the risk of preterm birth. • Cannot be used with PPIs • Requires consideration of timing when dosed with H2 blockers, which are commonly used during pregnancy (see Table 14).
DRV/r plus a *Preferred* Dual-NRTI Backbone	• When a PI-based regimen is indicated, DRV/r is recommended over ATV. However, DRV/r requires twice-daily dosing in pregnancy, and dosing frequency affects adherence. For that reason, when use of a PI-based regimen is indicated during pregnancy, some Panel members would use ATV/r rather than DRV/r for ART. • DRV/r with a NRTI backbone of TAF or TDF with 3TC or FTC is the *Preferred* regimen for initial treatment in people with early (acute or recent) HIV infection *and* a history of CAB-LA exposure for PrEP, see Early (Acute or Recent) HIV Infection.	• Not available as an FDC • Requires twice-daily dosing during pregnancy • Requires administration with food • PIs may increase the risk of preterm birth.
Alternative Dual-NRTI Backbone	Advantages	Disadvantages
ZDV/3TC	• Available as an FDC • Significant experience during pregnancy	• Requires twice-daily dosing • Associated with higher rates of side effects, including nausea, headache, and reversible maternal and neonatal anemia and neutropenia • Other regimens have demonstrated similar or greater efficacy and fewer side effects.

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Alternative NNRTI Regimens	Advantages	Disadvantages
EFV/TDF/FTC (FDC) *or* EFV/TDF/3TC (FDC) *or* EFV plus a *Preferred* Dual-NRTI Backbone	• Once-daily dosing • Available as an FDC • Extensive experience in pregnancy • Not associated with increased risk of NTDs or other congenital anomalies in human studies (although cautionary text based on animal studies remains in the package insert); see Efavirenz and Table 14. • No dose changes required during pregnancy • Useful for patients who require treatment with drugs that have significant interactions with *Preferred* agents or who need the convenience of a coformulated, single-tablet, once-daily regimen and are not eligible for DTG	• Overall higher rates of adverse events than some *Preferred* drugs • Requires enhanced surveillance for depression and suicidality • Increased risk of adverse birth outcomes has been observed with EFV/TDF/FTC versus DTG/TAF/FTC started during pregnancy. • Increased risk of toxicity, including dizziness, fatigue, hepatotoxicity, vivid dreams/nightmares
RPV/TDF/FTC (FDC) *or* RPV/TAF/FTC (FDC) *or* RPV (oral) plus a *Preferred* Dual-NRTI Backbone	• Once-daily dosing • Available as an FDC • Useful for patients who require treatment with drugs that have significant interactions with *Preferred* agents or who need the convenience of a coformulated, single-tablet, once-daily regimen and are not eligible for DTG	• Limited use for individuals with high pre-treatment HIV RNA. RPV is not recommended in patients with pre-treatment HIV RNA >100,000 copies/mL or CD4 counts <200 cells/mm^3. • Requires close viral monitoring in second and third trimesters because PK data suggest lower drug levels. Insufficient data to suggest dosing changes. • Do not use with PPIs. • Requires consideration of timing when dosed with H2 blockers or PPIs, which are commonly used during pregnancy (see Table 14) • Requires administration with food

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Insufficient Data for Use as Initial Regimens in Pregnancy		
These drugs and drug combinations are approved for use in adults, but pregnancy-specific PK or safety data are too limited to make recommendations for use in pregnant people. When a pregnant person presents to care while virally suppressed on one of these drugs or drug combinations, providers should consider whether to continue their current regimen or switch to a recommended ARV regimen (see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant and Table 7). It is critical that providers report exposures to these medications in pregnancy to the Antiretroviral Pregnancy Registry.		
Insufficient Data	Advantages	Disadvantages
DOR *or* DOR/TDF/FTC	• Coformulated with TDF/FTC • No food requirement	• Limited PK, toxicity, and efficacy data in pregnancy • Initial studies suggest potentially lower drug levels in third trimester.

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Not Recommended for Use as Initial Regimens in Pregnancy		
Drugs and drug combinations listed in this category are *Not Recommended* for use in pregnancy because of inferior virologic efficacy or potentially serious safety concerns for the pregnant person or fetus or because they are not recommended for initial therapy in nonpregnant adults. This category includes drugs or drug combinations for which PK data demonstrate low drug levels and risk of viral rebound during pregnancy. Levels of these drugs are often low in late pregnancy (during the second and third trimesters), when risk for perinatal transmission is high if viremia in the pregnant person occurs (see Table 7 and Table 14). Note: When a pregnant person presents to care while virally suppressed on one of these drugs or drug combinations, providers should consider whether to continue their current regimen with more frequent viral load monitoring or switch to a *Preferred* ARV regimen (see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant and Table 7).		
Not Recommended	Advantages	Disadvantages
ATV/c		• Limited existing data suggest insufficient levels of both COBI and ATV in second and third trimesters. • Changing COBI component to RTV is likely to improve efficacy but will increase pill burden.
Long-Acting Injectable CAB plus RPV (Co-packaged Formulation)	• Injectable delivery may be more effective and/or more convenient than oral ART for some patients. • Approved for nonpregnant adults who have RNA levels <50 copies/mL for at least 3 months on a stable oral ARV regimen, with no history of treatment failure and no known or suspected resistance	• Limited PK, toxicity, and efficacy data during pregnancy • Not recommended as initial treatment for ARV-naive adults or adolescents (pregnant or nonpregnant) • Due to the long half-life of injectable CAB and RPV, drug levels may persist up to 12 months after the last dose. Optimal timing of switch to an oral regimen is not known (see Management of the Treatment-Experienced Patient in the Adult and Adolescent Antiretroviral Guidelines).
DRV/c (FDC) *or* DRV/c/FTC/TAF (FDC)	• DRV/c/FTC/TAF is coformulated as a single-tablet, once-daily regimen.	• Limited existing data suggest insufficient levels of both COBI and ATV in second and third trimesters; viral breakthroughs have been reported. • Changing COBI component to RTV is likely to improve efficacy but will increase pill burden; in addition to adding RTV as separate pill, both DRV and RTV should be dosed twice daily.
EVG/c/FTC/TAF (FDC) *or* EVG/c/FTC/TDF (FDC)	• Coformulated as single-tablet, once-daily regimen	• Limited existing data suggest insufficient levels of both COBI and EVG in second and third trimesters. • Viral breakthrough at delivery was identified in 26% of previously suppressed individuals in IMPAACT P1026. Data are insufficient to suggest dosing changes. • Unlike for DRV/c and ATV/c, there is no option to replace COBI with RTV boosting. • Specific timing and/or fasting recommendations apply, especially if taken with calcium or iron (e.g., in prenatal vitamins; see Table 14 and Elvitegravir for details).

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Not Recommended for Initial Use in Pregnancy, but May Be Used in Special Circumstances for Pregnant People Who Are Treatment-Experienced		
These drugs are *Not Recommended* for use in pregnant people who have never received ART. Except for NVP and LPV/r, data on the PK, safety, and efficacy of these drugs during pregnancy are limited. These drugs also are categorized as *Not Recommended* during pregnancy, except in special circumstances, because the Panel recognizes that circumstances may exist in which patients who are ART-experienced may need to initiate or continue these drugs during pregnancy to reach or maintain viral suppression (see Table 7).		
Not Recommended Except in Special Circumstances for Pregnant People Who Are Treatment-Experienced	Advantages	Disadvantages
ETR	• Standard adult dose is appropriate during pregnancy in the special circumstance where ETR is used.	• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy
FTR		• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy
IBA		• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy • Requires IV administration
LEN		• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy • Use is limited to multidrug-resistant HIV
LPV/r plus a *Preferred* Dual-NRTI Backbone	• Extensive experience during pregnancy • Available as a liquid formulation when needed. LPV/r solution contains approximately 42% (v/v) ethanol and 15% (w/v) propylene glycol; it should be used with caution in pregnancy.	• Not recommended in nonpregnant individuals who are ART-naive • Requires twice-daily dosing in pregnancy; data suggest that once-daily LPV/r will not achieve sufficient plasma concentrations. • Some experts recommend increased dosing in the second and third trimesters (see Table 14 and Lopinavir/Ritonavir). • Associated with nausea and diarrhea • Associated with increased risk of preterm birth and small-for-gestational-age neonatal status (see Antiretroviral Drug Regimens and Pregnancy Outcomes)

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MVC	• Limited data suggest standard adult dose is appropriate during pregnancy.	• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy • Requires tropism testing before use
NVP	• Standard adult dosing is appropriate in pregnancy in the special circumstance where NVP is used.	• Not recommended in nonpregnant individuals who are ART-naive • Greater potential for adverse effects • Low barrier to resistance • Requires complex lead-in dosing • NVP should be used with caution when initiating ART in women with CD4 counts >250 cells/mm^3. • Use NVP and ABC together with caution; both can cause hypersensitivity reactions in the first few weeks after initiation.
T-20		• Not recommended in nonpregnant individuals who are ART-naive • Limited PK, toxicity, and efficacy data during pregnancy

Note: The following drugs and drug combinations (not listed above) should not be used during pregnancy; people who become pregnant while taking these medications should switch to a recommended regimen: d4T, ddI, FPV, FPV/r, IDV, IDV/r, NFV, RTV (as the sole PI), SQV, SQV/r, TPV, TPV/r, two-drug ARV regimens, or a three-NRTI ARV regimen (e.g., ABC/ZDV/3TC). See Archived Drugs in the Perinatal Guidelines and What Not to Use in the Adult and Adolescent Antiretroviral Guidelines for individual ARV drugs, ARV combinations, and ARV regimens that are not recommended or that should not be used in adults.

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; CD4 = CD4 T lymphocyte; CAB = cabotegravir; CAB-LA = long-acting cabotegravir; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EC_{95} = 95% maximal effective concentration; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDC = fixed-dose combination; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; FTR = fostemsavir; HBV = hepatitis B virus; HD = high dose; IBA = ibalizumab; IDV = indinavir; IDV/r = indinavir/ritonavir; IMPAACT = International Maternal Pediatric Adolescent AIDS Clinical Trials; INSTI = integrase strand transfer inhibitor; IV = intravenous; LEN = lenacapavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NTD = neural tube defect; NVP = nevirapine; the Panel = the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission; PI = protease inhibitor; PK = pharmacokinetic; PPI = proton pump inhibitor; PrEP = pre-exposure prophylaxis; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQV = saquinavir; SQV/r = saquinavir/ritonavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; ZDV = zidovudine