Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States

Developed by the HHS Panel on Treatment of
HIV During Pregnancy and Prevention of Perinatal Transmission—
A Working Group of the NIH Office of AIDS Research Advisory Council (OARAC)

How to Cite the Perinatal Guidelines:

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It is emphasized that concepts relevant to HIV management evolve rapidly. The Panels have a mechanism to update recommendations on a regular basis, and the most recent information is available on the Clinicalinfo website (https://clinicalinfo.hiv.gov/).

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Table 1. Outline of the Guidelines Development Process

Topic	Comment
Goal of the Guidelines	Provide guidance to HIV care practitioners in the United States on the optimal use of antiretroviral (ARV) agents to treat pregnant people with HIV, prevent HIV acquisition during pregnancy, and prevent perinatal HIV transmission in infants exposed to HIV.
Panel Members	The Panel is composed of approximately 41 voting members who have expertise in managing the care of pregnant people with HIV (e.g., training in obstetrics/gynecology, infectious diseases, or women's health), the pharmacology of ARV drugs during pregnancy, and the interventions for prevention of perinatal transmission (e.g., specialized training in pediatric HIV infection). The Panel also includes community representatives with knowledge of HIV infection in pregnant people and interventions for the prevention of perinatal transmission. The U.S. government representatives, appointed by their agencies, include at least one representative from each of the following U.S. Department of Health and Human Services agencies: Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), and National Institutes of Health (NIH). Members who do not represent U.S. government agencies are selected by Panel members after an open call for nominations. Each member serves on the Panel for a 3-year period, with an option for reappointment. The Panel also may include liaison members from the National Perinatal HIV hotline, the American Academy of Pediatrics Committee on Pediatric AIDS, the American College of Obstetricians and Gynecologists, the Society of Obstetricians and Gynaecologists of Canada, and the Canadian Pediatric and Perinatal Research Group. A list of all Panel members can be found in the Guidelines Panel Members section.
Financial Disclosures	All members of the Panel submit an annual written financial disclosure that reports any association with manufacturers of ARV drugs or diagnostics used to manage HIV infection. See Financial Disclosure for a list of the latest disclosures.
Users of the Guidelines	Providers of care to pregnant people with HIV and infants who have been exposed to HIV
Developer	The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission—a working group of the Office of AIDS Research Advisory Council (OARAC)
Funding Source	Office of AIDS Research, NIH
Evidence for Recommendations	The recommendations in these guidelines are generally based on studies published in peer-reviewed journals. On some occasions, particularly when new information may affect patient safety, unpublished data that were presented at major conferences or prepared by FDA and/or manufacturers as warnings to the public may be used as evidence to revise the guidelines.
Recommendation Grading	See Table 2.

Table 1. Outline of the Guidelines Development Process

Topic	Comment
Method of Synthesizing Data	Each section of the guidelines is assigned to a small group of Panel members with expertise in the area of interest. A structured literature search is conducted by a technical assistance consultant and provided to the Panel working group. The members review and synthesize the available data and propose recommendations to the entire Panel. The Panel discusses all proposals during monthly teleconferences. Proposals are modified based on Panel discussions and then distributed, with ballots, to all Panel members. If substantive comments or votes against approval are made, the recommended changes and areas of disagreement are brought back to the full Panel (via email or teleconference) for review, discussion, and further modification to reach a final version that is acceptable to all Panel members. The recommendations in these final versions represent the consensus of Panel members and are included in the guidelines as official Panel recommendations.
Other Guidelines	These guidelines focus on pregnant people with HIV and their infants. Other guidelines (all of which are available on the Clinicalinfo website) outline the use of ARV agents in nonpregnant adults and adolescents with HIV; use of ARV agents in infants and children with HIV; treatment and prevention of opportunistic infections (OIs) in adults and adolescents with HIV, including pregnant people; treatment and prevention of OIs in children who have been exposed to HIV or who have HIV infection; and treatment of people who experience occupational or nonoccupational exposure to HIV. Preconception management for nonpregnant people of reproductive potential is discussed briefly in this document. However, for a more detailed discussion of the issues surrounding the treatment of nonpregnant adults, please consult the Adult and Adolescent Antiretroviral Guidelines and the Adult and Adolescent Opportunistic Infection Guidelines.
Update Plan	The Panel meets monthly by teleconference to review data that may affect the content of the guidelines. Updates may be prompted by new drug approvals (or new indications, new dosing formulations, and/or changes in dosing frequency), significant new safety or efficacy data, or other information that may have a significant impact on the clinical care of patients. In the event of significant new data that may affect patient safety, the Panel may issue a warning announcement and recommendations on the Clinicalinfo website until the guidelines can be updated with the appropriate changes.
Public Comments	A 2-week public comment period follows the release of the updated guidelines on the Clinicalinfo website. The Panel reviews comments to determine whether additional revisions to the guidelines are indicated. The public also may submit comments to the Panel at any time at HIVinfo@NIH.gov.

Basis for Recommendations

The recommendations in these guidelines are based on scientific evidence and expert opinion. Each recommendation statement includes a letter **(A, B,** or **C)** that represents the strength of the recommendation and a Roman numeral **(I, II,** or **III)** that represents the quality of the evidence that supports the recommendation.

Table 2. Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for Recommendation
A: Strong recommendation for the statement B: Moderate recommendation for the statement C: Optional recommendation for the statement	I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes III: Expert opinion

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraceptives

Note: All recommendations in this table are based on consensus expert opinion. Additional information can be found in the Centers for Disease Control and Prevention Update to U.S. Medical Eligibility Criteria for Contraceptive Use, 2016: Updated Recommendations for the Use of Contraception Among Women at High Risk for HIV Infection.

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)	
Efavirenz (EFV)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, and ENG Implants	If efficacy is of primary importance, consider an alternative method (or a reliable method of barrier contraception in addition to this method).
Dosing Recommendation/Clinical Comment for DMPA[a]	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • No effect on EE concentrations • ↓ active metabolites of norgestimate; LNG AUC ↓ 83% and norelgestromin AUC ↓ 64%[40] • ENG (in COC) C_{24h} ↓ 61%[46] • ENG ↓ 79%; EE ↓ 59%[57] DMPA • No effect on DMPA levels[37,39] • DMPA AUC ↓ 33-35% when coadministered with EFV, rifampin, and INH. More frequent DMPA dosing may be appropriate.[69] ENG Implant • ENG ↓ below the level necessary to prevent pregnancy (90 pg/mL) in 60% of people on EFV[74] • ↓ 49% ENG concentration[56] • ENG AUC ↓ 63% to 82%[64,75] LNG Implant • ↓ 61% LNG concentration[56] • LNG AUC ↓ 47%[51] • ↑ pregnancy incidence rate among women using LNG or ENG implants, more among ENG users[66] • LNG AUC ↓ 40–73% over 30 months of use[67] • Doubling the dose of LNG implant from 150 mg to 300 mg did not overcome the decrease in LNG concentration.[58]

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

	LNG Emergency Contraception (Oral Dosing) • LNG (emergency contraception) AUC ↓ 58%[22] • C_{max} was 51% higher with 3 mg LNG (24.9 ng/mL) compared to 1.5 mg (15.1 ng/mL), and the 48-hour concentration was 66% higher (0.6 vs. 0.3 ng/mL, respectively). Dose adjustment of LNG EC from 1.5 mg to 3 mg helped to overcome the drug–drug interaction in women receiving EFV-based ART.[23] Vaginally Administered ENG/EE (Vaginal Ring) • ENG ↓ 93% in CYP2B6 slow metabolizers and ↓ 75% in normal and intermediate metabolizers[68] • EE ↓ 75% in slow metabolizers and ↓ 41% in normal and intermediate metabolizers[68] Changes in ARV Levels and/or Effects on HIV *COC* • No effect on EFV concentrations[40] • EFV C_{12h} ↓ 22%; under therapeutic threshold in 3 of 16 subjects[46] *DMPA* • No effect on HIV disease progression[37,76,77] • No effect on EFV concentrations[37] LNG Implant • No effect on HIV disease progression[51]
Clinical Studies	COC • No difference in pregnancy rates[65] • Pregnancy rate was 13% higher in women using COCs and EFV than in women using COCs alone.[63,78] • Progesterone >3 ng/mL (a surrogate for ovulation) in 3 of 16 women[79] • No ovulations[40] DMPA • No increase in pregnancies[37,63,65,77] • Low endogenous progesterone, consistent with no ovulation[37,39,77] ENG Implant • Pregnancy rate higher with EFV compared with no ART but still lower with implants than with other hormonal methods of contraception[63] • Presumptive ovulation in 5%[75] LNG Implant • 12% pregnancy rate[47] • 15% pregnancy rate[51]

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

	• Pregnancy rate higher with EFV compared with no ART but still lower with implants than with other hormonal methods of contraception[63] • No increase in pregnancy rate[65]
Justification/Evidence for Recommendation	For COCs, some studies suggest higher pregnancy rate and ovulation rate and decreased progestin levels. EFV may decrease, but clinical significance is unclear. For DMPA, evidence does not show effects on pregnancy rate, ovulation, or DMPA levels. Also, no effect on HIV disease progression or EFV levels. More frequent DMPA dosing may be appropriate for women receiving rifampicin, INH, and EFV. For implants, some studies suggest higher pregnancy rate and decreased hormone levels. For vaginally administered ENG/EE, PK evaluation showed that ENG levels were 79% lower and EE levels were 59% lower in participants on EFV than in controls after 21 days.[57]
Etravirine (ETR)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↑ 22%[80] No significant effect on NE[80]
Clinical Studies	COC • No ovulations[80]
Justification/Evidence for Recommendation	For COCs, one study found no ovulations and no significant change in progestin levels. No data on POPs
Nevirapine (NVP)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↓ 29%[81]; no change in EE AUC[82] NE AUC ↓ 18%[81] ENG (in COC) C_{24h} ↓ 22%[46] DMPA • No significant change[37] LNG Implant • LNG AUC ↑ 35%[51]

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

	• ↑ pregnancy incidence rate among women using LNG or ENG implants, more among ENG users[66] Changes in ARV Levels and/or Effects on HIV *COC* • No significant effect on NVP levels[79,81,83] *DMPA* • No effect on HIV disease progression[37,76,77,84] *LNG Implant* • No effect on HIV disease progression[51,85]
Clinical Studies	COC • No increase in pregnancy rate[63,65,78,86,87] • No ovulations[79,82,87] DMPA • No increase in pregnancy rates[63,65,77,86] • Low serum progesterone, consistent with no ovulation[37] ENG Implant • No increase in pregnancy rate[63] LNG Implant • No increase in pregnancy rate[47,51,63,65,85]
Justification/Evidence for Recommendation	For COCs, evidence does not show effects on pregnancy rate or ovulations. Evidence demonstrated a small decrease in progestin levels. No effect on NVP levels. For DMPA, evidence does not show effects on pregnancy rate, ovulation, or DMPA levels. No effect on HIV disease progression. For implants, evidence does not show effects on pregnancy rate or HIV disease progression.
Rilpivirine (Oral RPV)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↑ 14%[45] No significant change on NE[45] Changes in ARV Levels and/or Effects on HIV *COC* • No change in RPV levels compared to historical controls[45]

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

Clinical Studies	COC • No change in progesterone[45]
Justification/Evidence for Recommendation	For COCs, evidence does not show effects on ovulation or progestin levels. No change in RPV levels. No data on POPs
Doravirine (DOR)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	No clinically significant interaction with EE and LNG[88]
Clinical Studies	N/A
Justification/Evidence for Recommendation	No clinical data
Ritonavir (RTV)–Boosted Protease Inhibitors (PIs)	
Atazanavir/Ritonavir (ATV/r)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↓ 19%[89] Norgestimate AUC ↑ 85%[89] POP • NE AUC ↑ 50%[90] Vaginally Administered ENG/EE • ENG ↑ 71% • EE ↓ 38%[57]
Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, increase in progestin levels seen in only one study. Using a COC with at least 35 mcg/day may decrease breakthrough bleeding. For POPs, increase in progestin levels seen in only one study RTV inhibits CYP3A4, which may increase contraceptive hormone levels.
Darunavir/Ritonavir (DRV/r)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, and ENG Implants	If efficacy is of primary importance, can consider an alternative method (or a reliable method of barrier contraception in addition to this method)
Dosing Recommendation/Clinical Comment for DMPA[a]	No additional contraceptive protection is needed.

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↓ 44%[60] NE AUC ↓ 14%[60]
Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, small decrease in progestin levels No data on POPs
Lopinavir/Ritonavir (LPV/r)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	EE AUC ↓ 55%[36] NE AUC ↓ 17% Patch • EE AUC ↓ 45%[36] • Norelgestromin AUC ↑ 83%[36] DMPA • DMPA AUC ↑ 46%[49] ENG Implant • ENG AUC ↑ 52%[75] Changes in ARV Levels and/or Effects on HIV *Patch* • LPV/r ↓ 19%[36] *DMPA* • No effect on HIV disease progression[49] • No change in LPV/r levels[49]
Clinical Studies	COC • Trend of increased pregnancy rate, but CIs overlap[63] Patch • Low serum progesterone consistent with no ovulations (n = 8)[36] DMPA • No pregnancies and no ovulations[49] • Trend of increased pregnancy rate, but CIs overlap[63] ENG Implant • No increase in pregnancy rate[63]

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	LNG Implant • No increase in pregnancy rate[47,63]
Justification/Evidence for Recommendation	For COCs, nonsignificant increase in pregnancy rate. Small decrease in progestin level. For patch, no ovulations, and progestin levels increased For DMPA, evidence shows no effect on pregnancy rate or ovulations. Progestin levels increased. For implants, evidence shows no effect on pregnancy rate. Progestin levels increased.
Cobicistat (COBI)-Boosted Protease Inhibitors (PIs)	
Atazanavir/Cobicistat (ATV/c)	
Dosing Recommendation/Clinical Comment for COC/P/R	**Contraindicated** with drospirenone-containing hormonal contraceptives due to potential for hyperkalemia
Dosing Recommendation/Clinical Comment for POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	Drospirenone AUC ↑ 2.3-fold[54] No change in LNG concentration 25% decrease in EE C24[53]
Clinical Studies	N/A
Justification/Evidence for Recommendation	No data on POPs
Darunavir/Cobicistat (DRV/c)	
Dosing Recommendation/Clinical Comment for COC/P/R	Clinical monitoring is recommended when DRV/c is used in combination with drospirenone-containing COCs as a result of the potential for hyperkalemia.
Dosing Recommendation/Clinical Comment for POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	Drospirenone AUC ↑ 1.6-fold EE AUC ↓ 30%[54]
Clinical Studies	N/A
Justification/Evidence for Recommendation	No data on POPs
Protease Inhibitors (PIs) without Ritonavir (RTV)	
Atazanavir (ATV)	
Dosing Recommendation/Clinical Comment for COC/P/R	Prescribe oral contraceptive that contains no more than 30 mcg of EE or recommend alternative contraceptive method.

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Dosing Recommendation/Clinical Comment for POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • EE AUC ↑ 48%[91] • NE AUC ↑ 110%[91]
Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, increased concentrations of estrogen and progestin, but the only data available are from the product label. No data on POPs
CCR5 Antagonist	
Maraviroc (MVC)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • No significant effect on EE or LN[92]
Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, no change in EE or progestin. No clinical data. No data on POPs
Integrase Strand Transfer Inhibitors (INSTIs)	
Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	No significant drug interactions with EE or norgestimate
Clinical Studies	N/A
Justification/Evidence for Recommendation	No clinical data
Dolutegravir (DTG)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • No significant effect on ENG implants[74] • No significant effect on norgestimate or EE • No change in DTG AUC[50]

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, no change in EE or progestin. No clinical data. No data on POPs
Elvitegravir/Cobicistat (EVG/c)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • Norgestimate AUC ↑ 126% • EE AUC ↓ 25%[93,94]
Clinical Studies	N/A
Justification/Evidence for Recommendation	When administered as the four-drug regimen EVG/c/FTC/TDF, increases in progestin and a small decrease in EE were observed. No clinical data. No data on POPs
Raltegravir (RAL)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection is needed.
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	COC • No change in EE • Norgestimate AUC ↑ 14%[95]
Clinical Studies	N/A
Justification/Evidence for Recommendation	For COCs, no change in EE and a small increase in progestin. No clinical data. No data on POPs.
Long-Acting Cabotegravir (CAB-LA)	
Dosing Recommendation/Clinical Comment for COC/P/R, POPs, DMPA[a], ENG Implants	No additional contraceptive protection needed
Effect on Contraceptive Drug Levels and Contraceptive's Effects on ART and HIV	Oral contraceptive use was associated with ↓ CAB-LA C_{max} compared to women not on any hormonal contraception (GMR 0.75; 90% CI, 0.59–0.93; $P = 0.033$). However, oral contraceptive use did not result in significant differences in other CAB-LA PK parameters.
Clinical Studies	N/A
Justification/Evidence for Recommendation	Although oral contraceptive use was associated with lower CAB-LA peak concentration, no other PK parameters seen suggesting the association is not likely to be clinically significant.

[a] Because the hormonal levels achieved with DMPA are substantially higher than the levels that are required for contraception, any small reduction in hormonal level attributed to ARV drugs is unlikely to reduce contraceptive effectiveness.

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraception

Key to Symbols:

↑ = increase
↓ = decrease

Key: ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; AUC = area under the curve; BIC = bictegravir; C_{12h} = concentration at 12 hours postdose; C_{24h} = concentration at 24 hours postdose; CAB-LA = long-acting cabotegravir; CI = confidence interval; $C_{max;}$ = minimum plasma concentration; COBI = cobicistat; COC = combined oral contraceptives; COC/P/R = COC/patch/ring; CYP = cytochrome P450; DMPA = depot medroxyprogesterone acetate; DOR = doravirine; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EC = emergency contraception; EE = ethinyl estradiol; EFV = efavirenz; ENG = etonogestrel; ETR = etravirine; EVG/c = elvitegravir/cobicistat; FTC = emtricitabine; GMR = geometric mean ratio; INH = isoniazid; INSTI = integrase strand transfer inhibitor; LNG = levonorgestrel; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NE = norethindrone; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; POP = progesterone-only oral contraceptive pills; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

Sources: Panel on Antiretroviral Guidelines for Adults and Adolescents; Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV; Table 24a, Table 24b, and Table 24d

Table 4. Antepartum Screenings and Assessments for Pregnant People with HIV[a]

Antepartum Screenings and Assessments	At Entry into Antenatal Care	At Each Visit	As Clinically Indicated
Assessment of ART adherence, adherence challenges, and facilitators	✓	✓	✓
Assessment of the need for prophylaxis against opportunistic infections, e.g., *Pneumocystis jirovecii* pneumonia[b]	✓		✓
Screening for HAV, HBV, and HCV and assessment of vaccination or treatment needs[c]	✓		
Assessment and provision of other vaccination needs, e.g., influenza, pneumococcus, Tdap, SARS-CoV-2 (including boosters)[d]	✓		✓
Tuberculosis screening[e]	✓		✓
STI screening, e.g., syphilis, *Chlamydia trachomatis*, *Trichomonas vaginalis*, and *Neisseria gonorrhea*	✓		✓[f]
Screening for depression and anxiety	✓		✓
Screening for IPV	✓		✓
Assessment of the patient's gender identity and pronouns[g]	✓		
Assessment of the need for supportive care, e.g., social services, mental health services, substance use disorder treatment services, smoking cessation	✓	✓	✓

[a] Provide or refer for needed services based on the results of screenings and assessments, e.g., immunizations, treatment, referrals.

[b] Prophylaxis against *Pneumocystis jirovecii* pneumonia is recommended during pregnancy when CD4 count is <200 cells/mL. See Pneumocystis Pneumonia in the Adult and Adolescent Opportunistic Infections Guidelines.

[c] See Hepatitis B Virus/HIV Coinfection and Hepatitis C Virus/HIV Coinfection for guidance regarding immunizations and treatment.

[d] See Pregnancy and Vaccination and Maternal Immunizations for additional information.

[e] Includes screening for active and latent tuberculosis; stepwise screening for active tuberculosis may begin with exposure history and symptom screening (see Mycobacterium tuberculosis Infection and Disease). If screening for latent tuberculosis was performed and negative in the last year, repeat testing is not necessary for those at low risk for repeated or ongoing exposure to people with active tuberculosis.

[f] Repeat STI screening, particularly for syphilis, chlamydia, and gonorrhea, is often repeated in the third trimester (see Recommended Clinician Timeline for Screening for Syphilis, HIV, HBV, HCV, Chlamydia, and Gonorrhea).

[g] See Perinatal HIV Prevention for Transgender and Gender-Diverse People Assigned Female at Birth for additional guidance.

Key: ART = antiretroviral therapy; HAV = hepatitis A virus; HBV = hepatitis B virus; HCV = hepatitis C virus; IPV = intimate partner violence; STI = sexually transmitted infection; Tdap = tetanus, diphtheria, and pertussis vaccine

Table 5. HIV-Related Laboratory Monitoring Schedule for Pregnant People with HIV[a]

Laboratory Test	Timepoint or Frequency of Testing						
	Entry Into Antenatal Care[c]	ART Initiation or Modification	2 to 4 Weeks After ART Initiation or Modification	Monthly	Every 3 Months During Pregnancy	At 24 to 28 Weeks Gestation	At Approximately 36 Weeks of Gestation or Within 4 Weeks of Planned Delivery to Inform Mode of Delivery and Infant ARV Regimen
HIV RNA Levels[b]	✓[c]	✓ If a result is not available within 2 weeks of ART initiation or modification	✓	✓ Until HIV RNA levels are undetectable	✓ At least every 3 months[d]		✓
CD4 Count[e]	✓[c]				✓ Patients who have been on ART for <2 years and have CD4 counts of <300 cells/mm^3, those with inconsistent adherence, or those with detectable viral loads should have CD4 counts monitored every		

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	Entry Into Antenatal Care[c]	ART Initiation or Modification	2 to 4 Weeks After ART Initiation or Modification	Monthly	Every 3 Months During Pregnancy	At 24 to 28 Weeks Gestation	At Approximately 36 Weeks of Gestation or Within 4 Weeks of Planned Delivery to Inform Mode of Delivery and Infant ARV Regimen
					3 months during pregnancy.[e]		
Resistance Testing[f]		✓					
HLA-B*5701 Testing		✓ If abacavir use is anticipated					
Standard Screening for Gestational Diabetes[g]						✓	
Complete Blood Cell Count; Renal Function	✓	✓ With additional testing as clinically indicated				✓	

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Laboratory Test	Timepoint or Frequency of Testing						
	Entry Into Antenatal Care[c]	ART Initiation or Modification	2 to 4 Weeks After ART Initiation or Modification	Monthly	Every 3 Months During Pregnancy	At 24 to 28 Weeks Gestation	At Approximately 36 Weeks of Gestation or Within 4 Weeks of Planned Delivery to Inform Mode of Delivery and Infant ARV Regimen
Liver Function	✓	✓			✓ With additional testing as clinically indicated		
Monitoring for ARV-Specific Toxicities[h]	Refer to the recommendations in the package inserts for the individual ARV drugs.						

[a] For additional information, see Laboratory Monitoring in the Adult and Adolescent Antiretroviral Guidelines.

[b] The plasma HIV RNA levels of pregnant people with HIV should be monitored at the initial antenatal visit with a review of prior HIV RNA levels (AI), 2 to 4 weeks after initiating (or changing) antiretroviral therapy (ART) (BI), monthly until RNA levels are undetectable (BIII), and then at least every 3 months during pregnancy (BIII). Obtain an HIV RNA level at the time of ART initiation or modification if a recent result within 2 weeks prior is not available.

[c] Prior HIV-related illnesses and past plasma HIV RNA levels and CD4 counts should be reviewed at entry into antenatal care.

[d] More frequent viral load monitoring (every 1–2 months) may be indicated for patients who are taking ARVs that have been shown to have reduced drug levels in the second and third trimesters (e.g., cobicistat, elvitegravir, rilpivirine) and are potentially at risk for loss of viral suppression (see Table 6, Table 7, and People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant).

[e] CD4 count should be measured at the initial antenatal visit (AI). Patients who have been on ART for ≥2 years and who have had consistent viral suppression and CD4 counts that are consistently >300 cells/mm^3 do not need to have their CD4 counts monitored after the initial antenatal visit during this pregnancy, per the Adult and Adolescent Antiretroviral Guidelines (CIII). Patients who have been on ART for <2 years and have CD4 counts of <300 cells/mm^3, those with inconsistent adherence, or those with detectable

Table 5. HIV-Related Laboratory Monitoring Schedule for Pregnant People with HIV

viral loads should have CD4 counts monitored every 3 months during pregnancy (CIII). Those on ART<2 years and with CD4 counts >300 cells/mm^3 should have CD4 monitored every 6 months.

[f] ARV drug-resistance testing (genotypic testing and, if indicated, phenotypic testing) should be performed in patients whose HIV RNA levels are above the threshold for standard resistance testing (usually >500 copies/mL to 1,000 copies/mL but may be possible for HIV RNA >200 to ≤500 copies in some laboratories). Testing should be performed before—

- Initiating ART in ARV-naive pregnant patients who have not been tested previously for ARV drug resistance (AII);
- Initiating ART in ARV-experienced pregnant patients (AIII); *or*
- Modifying ARV regimens for patients who become pregnant while receiving ARV drugs or patients who have suboptimal virologic response to ARV drugs that were started during pregnancy (AII).

ART should be initiated in pregnant patients prior to receiving the results of ARV-resistance tests. ART should be modified, if necessary, based on the results of the resistance tests (BIII).

[g] Patients who are taking ART during pregnancy should undergo standard gestational diabetes screening (AIII). Some experts suggest performing glucose screening early in pregnancy for patients who are receiving PI-based regimens that were initiated before pregnancy, in accordance with recommendations for patients who are at risk for glucose intolerance (BIII). For more information on PIs, see Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes.

[h] Laboratory testing to monitor complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs a person is receiving (AIII).

Key: ART = antiretroviral therapy; ARV = antiretroviral; CD4 = CD4 T lymphocyte

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

Updated: January 31, 2024
Reviewed: January 31, 2024

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.

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

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.)

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

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.

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

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.

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

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).

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

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.

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

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

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

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.

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

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).

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

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)
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

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

		• 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

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

Updated: January 31, 2024
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People should be given information about the benefits and risks of initiating an antiretroviral regimen or making changes to an existing regimen during pregnancy or when trying to conceive so that they can make informed decisions about their care (see Appendix C: Antiretroviral Counseling Guide for Health Care Providers). Patient autonomy and informed choice should be considered in all aspects of medical care, including HIV and obstetric care. These are primary guiding principles in all the recommendations of the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission.

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
Integrase Strand Transfer Inhibitor (INSTI) Drugs Used in combination with a dual–nucleoside reverse transcriptase inhibitor (NRTI) backbone[c,d]					
DTG[a]	Preferred[a]	Continue	Preferred[a]	Preferred	Preferred
BIC[a,e]	Alternative[a]	Continue	Alternative[a]	Alternative	Alternative
RAL	Alternative	Continue	Alternative	Alternative	Alternative
CAB[d] Oral (lead-in) Long-acting (IM)	Not recommended	Continue with frequent viral load monitoring or consider switching due to insufficient data[d]	Insufficient data	Insufficient data	Insufficient data
EVG/c[f]	Not recommended	Continue with frequent viral load monitoring or consider switching.	Not recommended	Not recommended	Not recommended

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
Protease Inhibitor (PI) Drugs Used in combination with a dual-NRTI backbone[c]					
ATV/r[g]	Alternative	Continue	Alternative	Alternative	Alternative
DRV/r[a,g]	Alternative[a]	Continue	Alternative[a]	Alternative	Alternative
LPV/r[g]	Not recommended, except in special circumstances	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
ATV/c[f]	Not recommended	Continue with frequent viral load monitoring or consider switching.	Not recommended	Not recommended	Not recommended
DRV/c[f]	Not recommended	Continue with frequent viral load monitoring or consider switching.	Not recommended	Not recommended	Not recommended

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) Drugs Used in combination with a dual-NRTI backbone[c,d]					
EFV	Alternative	Continue	Alternative	Alternative	Alternative
RPV[h] Oral	Alternative	Continue	Alternative	Alternative	Alternative
RPV Long-acting (IM)[d]	Not recommended	Continue with frequent viral load monitoring or consider switching due to insufficient data.[d]	Insufficient data	Insufficient data	Insufficient data
DOR[i]	Insufficient data	Continue with frequent viral load monitoring or consider switching due to insufficient data.	Insufficient data	Insufficient data	Insufficient data
ETR[j]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
NVP[j]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
NRTI Drugs[c,k]					
ABC[c,k]	Preferred[c]	Continue	Preferred[c]	Preferred	Preferred[c]
FTC	Preferred	Continue	Preferred	Preferred	Preferred

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
3TC	Preferred	Continue	Preferred	Preferred	Preferred
TDF[c]	Preferred[c]	Continue	Preferred	Preferred	Preferred
ZDV	Alternative	Continue	Alternative	Alternative	Alternative
TAF[c]	Preferred[c]	Continue	Preferred	Preferred	Preferred
Entry, Attachment, Fusion, and Capsid Inhibitor Drugs					
FTR[j]	Not recommended	Continue[j]	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
IBA[j]	Not recommended	Continue[j]	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
LEN[j]	Not recommended	Continue[j]	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
MVC[j]	Not recommended	Continue[j]	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
T-20[j]	Not recommended	Continue[j]	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
Fixed-Dose Combination (FDC) and Coadministered Regimens[e,l] The individual drug component that is most responsible for the overall recommendation is indicated in parentheses.					
DTG/ABC/3TC[a,c,k]	Preferred[a,c]	Continue	Preferred[a,c]	Preferred	Preferred[a,c]
BIC/FTC/TAF[e]	Alternative (BIC)	Continue	Alternative (BIC)	Alternative (BIC)	Alternative (BIC)
EFV/FTC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
EFV/3TC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
RPV/TDF/FTC[h]	Alternative (RPV)	Continue (RPV)	Alternative (RPV)	Alternative (RPV)	Alternative (RPV)
RPV/TAF/FTC[h]	Alternative	Continue	Alternative	Alternative	Alternative
DOR/3TC/TDF[i]	Insufficient data (DOR)	Continue with frequent viral load monitoring or consider switching due to insufficient data (DOR).	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)
IM CAB and RPV[d] As a complete regimen	Not recommended	Continue with frequent viral load monitoring or consider switching due to insufficient data.[d]	Insufficient data	Insufficient data	Insufficient data
DRV/c/FTC/TAF[f]	Not recommended (DRV/c)	Continue with frequent viral load monitoring or consider switching (DRV/c).	Not recommended (DRV/c)	Not recommended (DRV/c)	Not recommended (DRV/c)

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

ART Regimen Component	ART for Pregnant People Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for People Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant People Who Have Received ARV Drugs in the Past and Who Are Starting or Restarting ART[a]	New ART Regimen for Pregnant People Whose Current Regimen Is Not Well Tolerated and/or Is Not Fully Suppressive	ART for Nonpregnant People Who Are Trying to Conceive[b]
EVG/c/FTC/TDF[f]	Not recommended (EVG/c)	Continue with frequent viral load monitoring or consider switching (EVG/c).	Not recommended (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)
EVG/c/FTC/TAF[f]	Not recommended (EVG/c)	Continue with frequent viral load monitoring or consider switching (EVG/c).	Not recommended (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)
DTG/3TC As a complete regimen[m]	Not recommended	Continue with frequent viral load monitoring.	Not recommended	Not recommended	Not recommended
DTG/RPV As a complete regimen[m]	Not recommended	Continue with frequent viral load monitoring.[m]	Not recommended	Not recommended	Not recommended

[a] Do not initiate ARV regimens with components that have documented resistance or suspected resistance based on prior ARV exposure. DTG and BIC are not recommended for initial treatment in people with a history of CAB exposure for PrEP due to concerns about INSTI resistance mutations in the absence of INSTI genotype information; DRV/r is *Preferred* in this situation.

[b] This guidance is intended for people who are pregnant or trying to conceive. These recommendations are not intended for all people with HIV who might become pregnant.

[c] ABC plus 3TC, TDF plus FTC, TAF plus FTC, and TDF plus 3TC are *Preferred* dual-NRTI backbones, and ZDV plus 3TC is an *Alternative* dual-NRTI backbone for ARV regimens. ABC is not recommended as part of regimens for initial treatment of early (acute or recent) HIV infection because it requires HLA-B*5701 testing before use. When results of HLA-B*5701 testing are not available, use of TDF or TAF rather than ABC will avoid delays in initiating ART.

[d] Long-acting injectable formulations of CAB and RPV are available only as a co-packaged product. Coadministration of CAB plus RPV is a complete two-drug ART regimen for nonpregnant adults with HIV RNA levels <50 copies/mL for at least 3 months, on a stable ARV regimen, with no history of treatment failure, and with no known or suspected resistance to CAB or RPV. Oral lead-in dosing with CAB and RPV for at least 28 days may be used to assess tolerability before starting monthly long-acting IM injections. CAB plus RPV (oral or injectable) should not be administered with NRTIs or other ARV drugs. Oral and injectable CAB and injectable RPV are not recommended for initiation in pregnancy due to lack of dosing, PK, and safety data for injectable RPV and for injectable or oral CAB. However, people who conceive while suppressed on injectable CAB/RPV may have few other treatment options, and the Panel recommends a shared decision-making process to decide whether to continue this regimen with viral load monitoring every 1 to 2 months or to switch to a recommended oral regimen. If a switch is made, the timing of the switch must take into account the long half-life of the long-acting injectable formulations with persistence of the drug for up to 12 months. With the current dosing schedule of monthly injections, change to an oral regimen should occur within 4 weeks of the last CAB and RPV IM doses. Dosing recommendations, including guidance

for switching to an oral regimen, can be found in the prescribing information. (See Cabotegravir in the Perinatal Guidelines and Optimizing Antiretroviral Therapy in the Setting of Viral Suppression in the Adult and Adolescent Antiretroviral Guidelines.)

[e] Data about BIC in nonpregnant adults show efficacy. PK and safety data in pregnancy remain limited to small studies. No safety concerns have been observed. Drug levels are lower in pregnant people who are in the 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 95% maximal effective concentration during pregnancy and thus are anticipated to suppress viral load.

[f] DRV/c, EVG/c, and ATV/c are not recommended for use in pregnancy because of PK changes that pose a risk for low drug levels and viral rebound in the second and third trimesters. However, in cases where virologically suppressed pregnant people present to care on regimens that include these drugs, these drug combinations can be continued with frequent (every 1–2 months) viral load monitoring or can be switched to a recommended or alternative agent. If concerns about switching exist, see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant. If the cobicistat pharmacologic booster is replaced with RTV for ATV and DRV, attention to dosing in pregnancy is critical; in the second and third trimesters, higher doses of ATV are required if coadministered with TDF or antacids, and twice-daily dosing is required for DRV.

[g] DRV/r, rather than ATV/r, is recommended as an option for initial ART in nonpregnant adults. However, DRV/r requires twice-daily dosing in pregnancy, and dosing frequency affects ARV adherence. For these reasons, when use of a PI-based regimen is indicated during pregnancy, some Panel members would use ATV/r rather than DRV/r for initial ART. LPV/r is not recommended for use in pregnancy but may be needed in special circumstances because it is safe for use in pregnancy and provides an option if a liquid formulation is needed (e.g., G-tube administration). However, because LPV/r solution contains approximately 42% (v/v) ethanol and 15% (w/v) propylene glycol, it should be used with caution in pregnancy.

[h] Although PK data indicate that RPV plasma concentration is reduced during the second and third trimesters, the reduction is less than that seen with use of EVG/c or DRV/c. Higher-than-standard doses of RPV have not been studied, so data are insufficient to recommend a dose change in pregnancy. With standard dosing, viral load should be monitored more frequently (every 1–2 months).

[i] Data on the safety, PK, and dosing of DOR in pregnancy are limited. Viral load should be monitored more frequently (every 1–2 months). Because fewer than 200 first-trimester and periconception exposures have been reported in the Antiretroviral Pregnancy Registry, it is not yet possible to exclude a risk of birth defects greater than that in the general population. Please report all exposures to the Antiretroviral Pregnancy Registry.

[j] Although these drugs are not recommended for initial treatment in ART-naive pregnant people, in special circumstances, ART-experienced people may need to continue or initiate ETR, FTR, IBA, LEN, NVP, MVC, and T-20 to maintain or achieve viral suppression. Safety and efficacy data about the use of ETR, FTR, IBA, LEN, MVC, and T-20 in pregnancy are limited. For highly treatment-experienced patients, consider switching to a regimen approved for use in pregnancy, or for patients without therapeutic alternatives, continue with frequent (every 1–2 months) viral load monitoring and counsel patients that safety data are not available during pregnancy. NVP is not recommended for ART-naive people because it has a greater potential for adverse events than other NNRTIs, complex lead-in dosing, and a low barrier to resistance; however, if a pregnant person 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. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive and Nevirapine for more information.

[k] Testing for HLA-B*5701 identifies patients who are at risk of developing hypersensitivity reactions while taking ABC; testing should be performed and a patient should be documented as negative before initiating ABC.

[l] When using FDC tablets, refer to Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and the drug sections in Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy for information about the dosing and safety of individual components of the FDC tablet during pregnancy.

[m] Two-drug oral ARV regimens are not recommended for use in pregnancy due to lack of available data about use in pregnancy. However, pregnant people who present to care on an oral DTG/3TC or DTG/RPV regimen with successfully maintained virologic suppression can continue it with more frequent viral load monitoring (every 1–2 months) throughout pregnancy because the component drugs are recommended for use in pregnancy.

Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive

Note: The following drugs and drug combinations, which are not listed above, should not be used during pregnancy: d4T, ddI, FPV, FPV/r, IDV, IDV/r, NFV, RTV (as the sole PI), SQV, SQV/r, TPV, TPV/r, or a three-NRTI ARV regimen (e.g., ABC/ZDV/3TC). If a person becomes pregnant while taking any of these medications, they should switch to a recommended regimen. 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 AR.V regimens that are not recommended or should not be used in adults. Refer to the table above and Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy for People Who Are Antiretroviral-Naive for ARV regimens that are recommended for use in pregnancy.

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; CAB = cabotegravir; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG/c = elvitegravir/cobicistat; FDC = fixed-dose combination; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; FTR = fostemsavir; IBA = ibalizumab; IDV = indinavir; IDV/r = indinavir/ritonavir; IM = intramuscular; IM CAB and RPV = long-acting intramuscular formulations of cabotegravir and rilpivirine; INSTI = integrase strand transfer inhibitor; LEN = lenacapavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; the Panel = Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission; PI = protease inhibitor; PK = pharmacokinetic; 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

Table 8. Drug-Specific Risk Assessment by the Antiretroviral Pregnancy Registry

ARV Drug	Level of Risk Assessment	Risk Assessment Outcome
BIC, COBI, DRV, d4T, ddI, DTG, EVG, IDV, RAL, RPV, and TAF	Sufficient numbers of first-trimester exposures have been monitored to detect at least a 2-fold increase in the risk of overall birth defects.	No such increases detected.
3TC, ABC, ATV, EFV, FTC, LPV/r, NFV, NVP, RTV, TDF, and ZDV	Sufficient numbers of first-trimester exposures have been monitored to detect at least a 1.5-fold increase in the risk of overall birth defects and a twofold increase in the risk of birth defects in cardiovascular and genitourinary systems.	No such increases detected.
CAB, DOR, ETR, FTR, LEN, and T-20	Insufficient numbers of exposures reported to assess the level of risk.	Not available.

Key: 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; ATV = atazanavir; BIC = bictegravir; CAB = cabotegravir; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV = darunavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FTC = emtricitabine; FTR = fostemsavir; IDV = indinavir; LEN = lenacapavir; LPV/r = lopinavir/ritonavir; NFV = nelfinavir; NVP = nevirapine; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine

Table 9. Intrapartum Care and Recommended Interventions to Prevent Perinatal HIV Transmission for Pregnant People with HIV Based on HIV RNA Levels at the Time of Delivery

All individuals with HIV should be receiving antiretroviral therapy (ART) or initiate ART in pregnancy as early as possible to suppress HIV RNA to undetectable levels (<50 copies/mL).

HIV RNA at Time of Delivery Assessed at 36 Weeks Gestation or within 4 Weeks of Delivery				
	<50 copies/mL and on ART with No Concerns About Adherence[a]	**≥50 to ≤1,000** copies/mL	>1,000 copies/mL	Unknown HIV RNA ART Adherence Concerns[a] Not Receiving ART HIV Diagnosis in Labor
Intrapartum ART	Pregnant people should take their prescribed ART on schedule during labor and before scheduled cesarean delivery (CIII). In general, ARV regimens are initiated postpartum for people diagnosed with HIV during labor.			
Intrapartum IV ZDV	Not required (BII)	Not required but may be considered (CII); many experts recommend	Yes, recommended (AI)[b] IV ZDV: 1-hour loading dose at 2 mg/kg followed by a continuous ZDV infusion of 1 mg/kg for 2 hours (at least 3 hours total) (AII)	
Mode of Delivery	Normal vaginal delivery[c] (AII)	Normal vaginal delivery[c] (AII)	Scheduled cesarean delivery at 38 weeks gestation[d] (AII)	Individualized care; see footnote[d]
Artificial Rupture of Membranes[e]	Per standard obstetric indications (BII)	Avoid if possible (BIII)	Not applicable; cesarean delivery recommended	Avoid if possible, in people with detectable or unknown viral load who are not receiving a cesarean delivery (BIII)
Induction of Labor	Per standard obstetric indications, including use of oxytocin. Pregnant people with HIV RNA ≤1,000 copies/mL should NOT be routinely induced at 38 weeks gestation.		Not applicable; scheduled cesarean delivery recommended	Avoid if possible (BIII)
IUPC	Data not available for pregnant people with HIV; use IUPC with caution and only if clear obstetric indications exist.			
Fetal Scalp Electrodes for Fetal Monitoring	Avoid—particularly when the birthing parent's viral load is not suppressed (≥50 copies/mL) or is unknown—because of the potential risk of HIV transmission (BIII). See Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection.			
Operative Delivery with Forceps or a Vacuum Extractor	Per standard obstetric indications (BIII)	Avoid for pregnant people in the setting of viremia if possible (BIII)		
Delayed Cord Clamping	Per standard obstetric indications and care			

HIV RNA at Time of Delivery Assessed at 36 Weeks Gestation or within 4 Weeks of Delivery				
	<50 copies/mL and on ART with No Concerns About Adherence[a]	**≥50 to ≤1,000** copies/mL	>1,000 copies/mL	Unknown HIV RNA ART Adherence Concerns[a] Not Receiving ART HIV Diagnosis in Labor
Use of Methergine for Postpartum Hemorrhage	Due to potential drug interactions with some ARV drugs, consider a patient's ARV regimen when treating postpartum bleeding caused by uterine atony (BIII).[f]			
Infant ARVs and Infant Feeding	See Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection, Table 10, Table 11, Postpartum Follow-Up of People with HIV, and Infant Feeding for Individuals with HIV in the United States.			

Key: ART = antiretroviral therapy; ARV = antiretroviral; CYP = cytochrome P450; IUPC = intrauterine pressure catheter; IV = intravenous; ZDV = zidovudine

[a] Assess ART adherence at every visit and upon presentation for delivery.

[b] Begin IV ZDV when patients present in labor or at least 3 hours before a cesarean delivery using a 1-hour loading dose of ZDV at 2 mg/kg followed by a continuous ZDV infusion of 1 mg/kg for at least 2 hours (AII).

[c] Scheduled cesarean delivery performed solely for prevention of perinatal HIV transmission in people receiving ART with HIV RNA ≤1,000 copies/mL is not recommended given the low rate of perinatal transmission in this group (AII). In people with HIV RNA levels ≤1,000 copies/mL, if scheduled cesarean delivery or induction is indicated, it should be performed at the standard time for obstetric indications (AII).

[d] Provide individualized care. If HIV RNA is >1,000 copies/mL or unknown, evidence is insufficient to determine whether cesarean delivery reduces the risk of perinatal HIV transmission for people who present in spontaneous labor or with ruptured membranes. Management of people originally scheduled for cesarean delivery because of HIV who present in labor must be individualized at the time of presentation (BII). In these circumstances, consultation with an expert in perinatal HIV (e.g., telephone consultation with the National Perinatal HIV/AIDS Clinical Consultation Center at 1-888-448-8765) may be helpful in rapidly developing an individualized plan.

[e] In pregnant people on ART with suppressed viral load (HIV RNA <50 copies/mL), duration of ruptured membranes is not associated with an increased risk of perinatal transmission and is not an indication for cesarean delivery to prevent HIV transmission (BII).

[f] Consider drug interactions with ART when treating postpartum bleeding caused by uterine atony. In people who are receiving a CYP3A4 enzyme inhibitor (e.g., a protease inhibitor, cobicistat), methergine should be used only if no alternative treatments for postpartum hemorrhage are available and the need for pharmacologic treatment outweighs the risks. If methergine is used, it should be administered at the lowest effective dose for the shortest possible duration (BIII). In people who are receiving a CYP3A4 enzyme inducer—such as nevirapine, efavirenz, or etravirine—additional uterotonic agents may be needed because of the potential for decreased methergine levels and inadequate treatment effect (BIII).

Rating of Recommendations: A = Strong; B = Moderate; C = Optional

Rating of Evidence: I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn

Drug selection and dosing considerations are related to the age and gestational age of the newborn. Consultation is available through the National Perinatal HIV hotline (1-888-448-8765) or from an expert in pediatric HIV infection.

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
Low Risk of Perinatal HIV Transmission	**Infants ≥37 weeks gestation when the** mother— • Is currently receiving and has received at least 10 consecutive weeks of ART during pregnancy, *and* • Has achieved and maintained *or* maintained viral suppression (defined as at least two consecutive tests with HIV RNA levels <50 copies/mL obtained at least 4 weeks apart) for the duration of pregnancy, *and* • Has HIV RNA <50 copies/mL at or after 36 weeks and within 4 weeks of delivery, *and* • Did not have acute HIV infection during pregnancy, *and* • Has reported good ART adherence, and adherence concerns have not been identified.	ZDV for 2 weeks[a]
	Infants born to mothers who do not meet the criteria above but who have a HIV RNA <50 copies/mL at or after 36 weeks gestation	ZDV for 4 to 6 weeks[a]
	Premature infants (<37 weeks gestation) who are not at high risk of perinatal acquisition of HIV	ZDV for 4 to 6 weeks[a]
High Risk of Perinatal HIV Transmission[a,b]	Mothers who did not receive antepartum ARV drugs, *or* Mothers who received only intrapartum ARV drugs, *or* Mothers who received antepartum ARV drugs but did not have viral suppression (defined as at least two consecutive tests with HIV RNA level <50 copies/mL obtained at least 4 weeks apart) within 4 weeks prior to delivery, *or* Mothers with acute or primary HIV infection during pregnancy or breastfeeding (in which case, breastfeeding should be immediately discontinued)[c]	Presumptive HIV therapy using either ZDV, 3TC, and NVP (treatment dose) *or* ZDV, 3TC, and RAL administered together from birth for 2 to 6 weeks; if the duration of the 3-drug regimen is shorter than 6 weeks, ZDV should be continued alone, to complete a total of 6 weeks of prophylaxis[d]

Table 10. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
Presumed Newborn HIV Exposure	Mothers with unconfirmed HIV status who have at least one positive HIV test at delivery or postpartum, *or* Mothers whose newborn has a positive HIV antibody test	ARV management as described above for newborns with a high risk of perinatal HIV acquisition Infant ARV drugs should be discontinued immediately if supplemental testing confirms that the mother does not have HIV.
Newborn With HIV[e]	Positive newborn HIV virologic test/NAT	Three-drug ARV regimen using treatment doses. Refer to the What to Start: Regimens Recommended for Initial Therapy of Antiretroviral-Naive Children in the Pediatric Antiretroviral Guidelines for specific treatment recommendations.

[a] ZDV prophylaxis is recommended for infants born to mothers with HIV-2 mono-infection; see HIV-2 Infection and Pregnancy. If the mother has HIV-1 and HIV-2 infection, the infant ARV regimen should be based on the determination of low or high risk of HIV-1 transmission as described in the above table. Because HIV-2 is not susceptible to NVP, RAL should be considered for infants at high risk of perinatal HIV-2 acquisition. See text for evidence that supports the use of presumptive HIV therapy and a two-drug ARV prophylaxis regimen.

[b] See Intrapartum Care for People With HIV for guidance on indications for scheduled cesarean delivery and intrapartum intravenous ZDV to reduce the risk of perinatal HIV transmission for mothers with an elevated viral load at delivery.

[c] Most Panel members would opt to administer presumptive HIV therapy to infants born to mothers with acute HIV infection during pregnancy because of the higher risk for *in utero* transmission. If acute HIV is diagnosed during breastfeeding, the mother should immediately discontinue breastfeeding.

[d] The optimal duration of presumptive HIV therapy in newborns who are at a high risk for HIV acquisition is unknown. Newborns who are at a high risk for HIV acquisition should receive the ZDV component of the three-drug presumptive HIV therapy regimen for 6 weeks. The other two ARVs (3TC and NVP *or* 3TC plus RAL) may be administered for 2 to 6 weeks; the recommended duration for treatment with three ARVs varies depends on infant HIV NAT results, maternal viral load at the time of delivery, and additional risk factors for HIV transmission including breastfeeding (see sections below). Consultation with an expert in pediatric HIV is recommended when selecting a therapy duration because this decision should be based on case-specific risk factors and interim infant HIV NAT results.

[e] Infant ART should be initiated without waiting for the results of confirmatory HIV NAT testing, given the low likelihood of a false-positive HIV NAT. However, the specimen for confirmatory HIV testing should be obtained prior to ART initiation.

Note: ARV drugs should be initiated as close to the time of birth as possible, preferably within 6 hours of delivery. See Table 11 for dosing specifics.

Key: 3TC = lamivudine; ART = antiretroviral therapy; ARV = antiretroviral; NAT = nucleic acid test; NVP = nevirapine; Panel = Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission and Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV; RAL = raltegravir; ZDV = zidovudine

Table 11. Antiretroviral Drug Dosing Recommendations for Newborns

<table>
<tr><th>Drug</th><th>Drug Doses by Gestational Age at Birth</th></tr>
<tr><td rowspan="3">ZDV

Note: For newborns who are unable to tolerate oral agents, the IV dose is 75% of the oral dose while maintaining the same dosing interval.</td><td>≥35 Weeks Gestation at Birth

Birth to Age 4 Weeks

• ZDV 4 mg/kg per dose orally twice daily or alternative simplified weight-band dosing (see below)

Age >4 Weeks

• ZDV 12 mg/kg per dose orally twice daily; only make this dose increase for infants with confirmed HIV infection.

Simplified Weight-Band Dosing for Newborns Aged ≥35 Weeks Gestation From Birth to 4 Weeks

<table><tr><th>Weight Band</th><th>Volume of ZDV 10 mg/mL Oral Syrup Twice Daily</th></tr><tr><td>2 to <3 kg</td><td>1 mL</td></tr><tr><td>3 to <4 kg</td><td>1.5 mL</td></tr><tr><td>4 to <5 kg</td><td>2 mL</td></tr></table></td></tr>
<tr><td>≥30 to <35 Weeks' Gestation at Birth

Birth to Age 2 Weeks

• ZDV 2 mg/kg per dose orally twice daily

Age 2 Weeks to 6 to 8 Weeks

• ZDV 3 mg/kg per dose orally twice daily

Age >6 to 8 Weeks

• ZDV 12 mg/kg per dose orally twice daily; make this dose increase only for infants with confirmed HIV infection.</td></tr>
<tr><td><30 Weeks' Gestation at Birth

Birth to Age 4 Weeks

• ZDV 2 mg/kg per dose orally twice daily

Age 4 to 8 to 10 Weeks

• ZDV 3 mg/kg per dose orally twice daily

Age >8 to 10 Weeks

• ZDV 12 mg/kg per dose orally twice daily; only make this dose increase for infants with confirmed HIV infection.</td></tr>
<tr><td>ABC[c]

Note: ABC is not approved by the FDA for use in neonates and infants aged <1 month. However, dosing</td><td>≥37 Weeks' Gestation at Birth

Birth to 1 Month

• ABC 2 mg/kg per dose orally twice daily</td></tr>
</table>

Table 11. Antiretroviral Drug Dosing Recommendations for Newborns

Drug	Drug Doses by Gestational Age at Birth
recommendations have been modeled using PK simulation. Because of ABC-associated hypersensitivity, negative testing for HLA-B5701 allele should be confirmed prior to administration of ABC.	*Age 1 Month to <3 Months* • ABC 4 mg/kg per dose orally twice daily
3TC	**≥32 Weeks' Gestation at Birth** *Birth to Age 4 Weeks* • 3TC 2 mg/kg per dose orally twice daily *Age >4 Weeks* • 3TC 4 mg/kg per dose orally twice daily
NVP[d]	**≥37 Weeks' Gestation at Birth** *Birth to Age 4 Weeks* • NVP 6 mg/kg per dose orally twice daily *Age >4 Weeks* • NVP 200 mg/m^2 BSA per dose orally twice daily; only make this dose increase for infants with confirmed HIV infection.
	≥34 to <37 Weeks' Gestation at Birth *Birth to Age 1 Week* • NVP 4 mg/kg per dose orally twice daily *Age 1 to 4 Weeks* • NVP 6 mg/kg per dose orally twice daily *Age >4 Weeks* • NVP 200 mg/m^2 BSA per dose orally twice daily; only make this dose increase for infants with confirmed HIV infection.
	≥32 to <34 Weeks' Gestation at Birth *Birth to Age 2 Weeks* • NVP 2 mg/kg per dose orally twice daily *Age 2 to 4 Weeks* • NVP 4 mg/kg per dose orally twice daily *Age 4 to 6 Weeks* • NVP 6 mg/kg per dose orally twice daily *Age >6 Weeks* • NVP 200 mg/m^2 BSA per dose orally twice daily; only make this dose increase for infants with confirmed HIV infection.

Table 11. Antiretroviral Drug Dosing Recommendations for Newborns

<table>
<tr><th>Drug</th><th>Drug Doses by Gestational Age at Birth</th></tr>
<tr><td>RAL

Note: If the mother has taken RAL 2 to 24 hours prior to delivery, the neonate's first dose of RAL should be delayed until 24 to 48 hours after birth; additional ARV drugs should be started as soon as possible.[7]</td><td>≥37 Weeks' Gestation at Birth and Weighing ≥2 kg[e]

Birth to Age 6 Weeks
<table>
<tr><th>Body Weight</th><th>Volume (Dose) of RAL 10 mg/mL Suspension</th></tr>
<tr><td>Birth to 1 Week: Once-Daily Dosing</td><td>Approximately 1.5 mg/kg per dose</td></tr>
<tr><td>2 to <3 kg</td><td>0.4 mL (4 mg) once daily</td></tr>
<tr><td>3 to <4 kg</td><td>0.5 mL (5 mg) once daily</td></tr>
<tr><td>4 to <5 kg</td><td>0.7 mL (7 mg) once daily</td></tr>
<tr><td>1 to 4 Weeks: Twice-Daily Dosing</td><td>Approximately 3 mg/kg per dose</td></tr>
<tr><td>2 to <3 kg</td><td>0.8 mL (8 mg) twice daily</td></tr>
<tr><td>3 to <4 kg</td><td>1 mL (10 mg) twice daily</td></tr>
<tr><td>4 to <5 kg</td><td>1.5 mL (15 mg) twice daily</td></tr>
<tr><td>4 to 6 Weeks: Twice-Daily Dosing</td><td>Approximately 6 mg/kg per dose</td></tr>
<tr><td>3 to <4 kg</td><td>2.5 mL (25 mg) twice daily</td></tr>
<tr><td>4 to <6 kg</td><td>3 mL (30 mg) twice daily</td></tr>
<tr><td>6 to <8 kg</td><td>4 mL (40 mg) twice daily</td></tr>
</table></td></tr>
</table>

[a] The optimal duration of presumptive HIV therapy in newborns who are at a high risk for perinatal HIV acquisition is unknown. Newborns who are at a high risk for HIV acquisition should receive the ZDV component of the three-drug presumptive HIV therapy regimen for 6 weeks. The other two ARVs (3TC and NVP *or* 3TC plus RAL) may be administered for 2 to 6 weeks; the recommended duration for these ARVs varies depending on infant HIV NAT results, maternal viral load at the time of delivery, and additional risk where increased risk of ZDV toxicity may exist, such as in infants with anemia or neutropenia. Because of ABC-associated hypersensitivity, negative testing for HLA-B5701 allele should be confirmed prior to administration of ABC.

[d] The NVP doses for infants ≥32 to <37 weeks gestation at birth and infants ≥37 weeks gestation at birth are not yet approved by the FDA. The FDA also has not approved a dose of NVP for infants aged <1 month. The doses for infants ≥32 to <34 weeks gestation at birth are based on modeling and might underestimate potential toxicity in infants of 32 to <34 weeks gestational age because the doses used to develop the model were lower than the doses now recommended. See Nevirapine in Appendix A: Pediatric Antiretroviral Drug Information in the Pediatric Antiretroviral Guidelines for additional information about dosing.

[e] RAL dosing is increased at 1 week and 4 weeks of age because metabolism by UGT1A1 is low at birth and increases rapidly during the next 4 to 6 weeks of life. No dosing information is available for preterm infants or infants weighing <2 kg at birth. In infants with HIV infection, twice-daily RAL can be replaced with once-daily DTG at ≥ 4 weeks of age (see Dolutegravir and What to Start: Regimens Recommended for Initial Therapy of Antiretroviral-Naive Children in the Pediatric Antiretroviral Guidelines). The current dosing regimen with two dose changes in the first month of life may be challenging for some families. To minimize dosing changes, some experts increase to the 3 mg/kg twice daily dose upon discharge on day 4 or 5 of life.

Table 11. Antiretroviral Drug Dosing Recommendations for Newborns

factors for HIV transmission. Consultation with an expert in pediatric HIV is recommended when selecting a therapy duration because this decision should be based on case-specific risk factors and interim infant HIV NAT results.

[b] For ARV management of infants with HIV infection, see the What to Start: Regimens Recommended for Initial Therapy of Antiretroviral-Naive Children section in the Pediatric Antiretroviral Guidelines.

[c] ABC is approved by the FDA for use in children aged ≥3 months when administered as part of an ARV regimen. ABC also has been reported to be safe in infants and children ≥1 month of age. More recently, an ABC dosing recommendation using PK simulation models has been endorsed by the WHO using weight-band dosing for full-term infants from birth to 1 month of age. See Abacavir in Appendix A: Pediatric Antiretroviral Drug Information in the Pediatric Antiretroviral Guidelines for additional information about the use of ABC between birth and 1 month of age. At this time, the Panels do not recommend ABC as part of a presumptive HIV therapy regimen. However, in situations where ZDV is not available or the infant has ZDV-associated toxicity, ABC could be considered an alternative to ZDV. This substitution should be considered in circumstances

Key: 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; BSA = body surface area; DTG = dolutegravir; FDA = U.S. Food and Drug Administration; IV = intravenous; NVP = nevirapine; the Panels = the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission and the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV; PK = pharmacokinetic; RAL = raltegravir; UGT = uridine diphosphate glucotransferase; WHO = World Health Organization; ZDV = zidovudine

Table 12. Infant Antiretroviral Prophylaxis for Newborns of Mothers with Sustained Viral Suppression Who Breastfeed

<table>
<tr><th colspan="2">Newborns at Low Risk of HIV Acquisition During Breastfeeding</th></tr>
<tr><th>Recommended Regimen</th><th>Recommended Duration</th></tr>
<tr><td>ZDV</td><td>ZDV administered for 2 weeks (see Table 11 for dosing)</td></tr>
<tr><th colspan="2">Optional Extended Postnatal Prophylaxis for Newborns at Low Risk of HIV Transmission During Breastfeeding</th></tr>
<tr><th>Optional Regimen</th><th>Optional Recommended Duration</th></tr>
<tr><td>ZDV</td><td>ZDV administered for 4 to 6 weeks (see Table11 for dosing)</td></tr>
<tr><td>NVP</td><td>Simplified Age-Based Dosing for Newborns ≥32 Weeks Gestation Receiving Extended NVP Prophylaxis During Breastfeeding[a]
<table>
<tr><th>Age</th><th>Volume of NVP 10 mg/mL Oral Syrup Daily</th></tr>
<tr><td>Birth to 6 weeks</td><td>1.5 mL</td></tr>
<tr><td>6 weeks to 6 months</td><td>2.0 mL</td></tr>
<tr><td>6 months to 9 months</td><td>3.0 mL</td></tr>
<tr><td>9 months to 1 to 4 weeks post-weaning</td><td>4.0 mL</td></tr>
</table></td></tr>
</table>

[a] Extended NVP prophylaxis during breastfeeding recommendations are adapted from the Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach. If prescribed, these simplified doses should start following confirmation of a negative infant NAT test and completion of a presumptive HIV therapy regimen in infants at high risk of HIV acquisition. For infants at low risk of transmission, these doses can be given from birth. Geneva: World Health Organization; 2021 Jul. Simplified Age-Based Dosing for Newborns ≥32 Weeks Gestation Receiving Extended NVP Prophylaxis During Breastfeeding in Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service delivery and Monitoring: Recommendations for a Public Health Approach.

[b] For breastfeeding parents with viral resistance to NVP, alternative regimens for infant prophylaxis after completion of the 4 to 6 weeks of presumptive HIV therapy include daily 3TC or LPV/r; see Table 11. Antiretroviral Drug Dosing Recommendations for Newborns for dosing information.

Table 13. Recommended Virologic Testing Schedules for Infants Who Were Exposed to HIV According to Risk of Perinatal HIV Acquisition at and After Birth

Infants at High Risk	
Criteria for Infants at High Risk	**Age at HIV NAT[b] Testing for Infants at High Risk**
Infants born to mothers with HIV who— • Did not receive prenatal care; • Received no antepartum ARVs or only intrapartum ARV drugs; • Initiated ART late in pregnancy (during the late second or third trimester); • Received a diagnosis of acute HIV infection during pregnancy or in labor; and/or • Had detectable HIV viral loads (≥50 copies/mL) close to the time of delivery, including those who received ART but did not achieve sustained viral suppression	Birth 14–21 days 1–2 months 2–3 months[c] 4–6 months All infants at high risk of perinatal HIV transmission should have specimens obtained for HIV testing at birth before initiating an ARV drug regimen; however, presumptive HIV therapy should not be delayed. If an infant's NAT test result is positive, a repeat test should be performed as soon as possible and ART should be initiated.
Infants at Low Risk	
Criteria for Infants at Low Risk	**Age at HIV NAT[b] Testing for Infants at Low Risk**
Infants born to mothers who— • Received ART during pregnancy; • Had sustained viral suppression (usually defined as <50 copies/mL); *and* • Were adherent to their ARV regimens	14–21 days 1–2 months[d] 4–6 months
Infants With Perinatal HIV Exposure Who Are Being Breastfed	
Age at HIV NAT[b] Testing for Infants With Perinatal HIV Exposure Who Are Being Breastfed	
Birth 14–21 days 1–2 months 2–4 months[e] 4–6 months If breastfeeding continues beyond 6 months of age, NAT testing should be performed every 3 months during breastfeeding. In addition to the standard time points after birth, NAT testing also should be performed at 4 to 6 weeks, 3 months, and 6 months after cessation of breastfeeding, regardless of the age at when breastfeeding ends. • Consultation with an expert is recommended to determine additional testing time points that may be needed for infants with risk factors for HIV acquisition at birth who are being breastfed. • Prompt NAT testing of the infa1-nt is indicated if maternal viral load becomes detectable during breastfeeding.	

Table 13. Recommended Virologic Testing Schedules for Infants Who Were Exposed to HIV According to Risk of Perinatal HIV Acquisition at and After Birth

If the mother has a detectable viral load and continues breastfeeding, some Panel members would recommend monthly virologic testing of the infant as an approach to early detection of HIV infection during ongoing exposure.

See Infant Feeding for Individuals With HIV in the United States. Consultation with an expert and/or the Perinatal HIV Hotline (1-888-448-8765) is recommended for questions about HIV diagnostic testing for infants with perinatal HIV exposure who are being breastfed.

[a] This table summarizes standard time points for HIV virologic diagnostic testing of infants according to risk of perinatal acquisition.

[b] HIV RNA or HIV DNA NATs that directly detect HIV.

[c] For high-risk infants, virologic diagnostic testing is recommended at birth. For infants treated with multiple ARVs in the first 2 to 4 weeks of life, additional virologic testing is recommended 2 to 6 weeks after ARV drugs are discontinued (i.e., at 8–12 weeks of life).

[d] For low-risk infants, testing may be timed to occur at least 2 weeks after cessation of ARV prophylaxis.

[e] An additional virologic test should be performed at age 2 to 4 months if the gap between the tests at ages 1 to 2 months and 4 to 6 months is greater than 3 months.

Key: ART = antiretroviral therapy; ARV = antiretroviral; NAT = nucleic acid test

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Updated: January 31, 2024
Reviewed: January 31, 2024

Note: When using fixed-dose combination (FDC) tablets, refer to other sections in Appendix B and Table 14 in the Perinatal Guidelines for information about the dosing and safety of individual drug components of the FDC tablet during pregnancy.

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
NRTIs NRTIs interfere with HIV reverse transcriptase by competitive inhibition. Nucleoside analogue drugs require three intracellular phosphorylation steps to form the triphosphate nucleoside, which is the active drug moiety. The nucleotide analogue tenofovir contains a monophosphate component attached to the adenine base and requires only two phosphorylation steps to form the active moiety.				
Abacavir (ABC) *Ziagen* (ABC/3TC) *Epzicom* (ABC/DTG/3TC) *Triumeq* (ABC/3TC/ZDV) *Trizivir* Note: Generic products are available for some formulations.	ABC (Ziagen)[c] *Tablet* • 300 mg *Oral Solution* • 20 mg/mL ABC/3TC (Epzicom)[c] • ABC 600-mg/3TC 300-mg tablet ABC/DTG/3TC (Triumeq) • ABC 600-mg/DTG 50-mg/3TC 300-mg tablet	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy *Dosing in Pregnancy* • No change in dose indicated For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, ZDV, DTG). Standard Adult Doses *ABC (Ziagen)* • ABC 300 mg twice daily or ABC 600 mg once daily, without regard to food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) HSRs occur in approximately 5% to 8% of nonpregnant individuals. A small percentage of reactions are fatal, and these fatal reactions are usually associated with re-challenge. Rate of reactions during pregnancy is unknown. Testing for HLA-B*5701 identifies patients at risk of reactions, and a patient's status should be documented as negative before initiating ABC. Patients should be educated regarding symptoms of HSR.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	ABC/3TC/ZDV (Trizivir)[c] • ABC 300-mg/3TC 150-mg/ZDV 300-mg tablet	*ABC/3TC (Epzicom)* • One tablet once daily without regard to food *ABC/DTG/3TC (Triumeq)* • One tablet once daily without regard to food *ABC/3TC/ZDV (Trizivir)* • One tablet twice daily without regard to food		
Emtricitabine (FTC) *Emtriva* (FTC/EFV/TDF) *Atripla* (FTC/BIC/TAF) *Biktarvy* (FTC/RPV/TDF) *Complera* (FTC/TAF) *Descovy* (FTC/EVG/c/TAF) *Genvoya* (FTC/RPV/TAF) *Odefsey* (FTC/EVG/c/TDF)	FTC (Emtriva) *Capsule*[c] • 200 mg *Oral Solution* • 10 mg/mL FTC/EFV/TDF (Atripla)[c] • FTC 200-mg/ EFV 60-mg/ TDF 300-mg tablet FTC/BIC/TAF (Biktarvy) • FTC 200-mg/ BIC 50-mg/ TAF 25-mg tablet FTC/RPV/TDF (Complera)	Pregnancy *PK in Pregnancy* • PK of FTC are not significantly altered in pregnancy. *Dosing in Pregnancy* • No change in dose indicated For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., TDF, TAF, EFV, RPV, DRV, EVG, BIC, COBI). Standard Adult Doses *FTC (Emtriva)* • Capsule o FTC 200 mg once daily without regard to food • Oral Solution	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Stribild (FTC/DRV/c/TAF) *Symtuza* (FTC/TDF) *Truvada* Note: Generic products are available for some formulations.	• FTC 200-mg/ RPV 25-mg/ TDF 300-mg tablet FTC/TAF (Descovy) • FTC 200-mg/ TAF 25-mg tablet FTC/EVG/c/TAF (Genvoya) • FTC 200-mg/ EVG 150-mg/ COBI 150-mg/ TAF 10-mg tablet FTC/RPV/TAF (Odefsey) • FTC 200-mg/ RPV 25-mg/ TAF 25-mg tablet FTC/EVG/c/TDF (Stribild) • FTC 200-mg/ EVG 150-mg/ COBI 150-mg/ TDF 300-mg tablet FTC/DRV/c/TAF (Symtuza) • FTC 200-mg/ DRV 800-mg/ COBI 150-mg/ TAF 10-mg tablet	○ FTC 240 mg (24 mL) once daily without regard to food *FTC/EFV/TDF (Atripla)* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce or mitigate side effects. *FTC/BIC/TAF (Biktarvy)* • One tablet once daily with or without food *FTC/RPV/TDF (Complera)* • One tablet once daily with food *FTC/TAF (Descovy)* • One tablet once daily with or without food *FTC/EVG/c/TAF (Genvoya)* • One tablet once daily with food *FTC/RPV/TAF (Odefsey)* • One tablet once daily with food *FTC/EVG/c/TDF (Stribild)* • One tablet once daily with food *FTC/DRV/c/TAF (Symtuza)* • One tablet once daily with food		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	FTC/TDF (Truvada)[c] • FTC 200-mg/ TDF 300-mg tablet	*FTC/TDF (Truvada)* • One tablet once daily without regard to food		
Lamivudine (3TC) *Epivir* (3TC/TDF) *Cimduo* (3TC/ZDV) *Combivir* (3TC/DOR/TDF) *Delstrigo* (3TC/DTG) *Dovato* (3TC/ABC) *Epzicom* (3TC/EFV/TDF) *Symfi* (3TC/EFV/TDF) *Symfi Lo* (3TC/TDF) *Temixys* (3TC/ABC/DTG)	3TC (Epivir)[c] *Tablets* • 150 mg • 300 mg *Oral Solution* • 10 mg/mL 3TC/TDF (Cimduo) • 3TC 300-mg/TDF 300-mg tablet 3TC/ZDV (Combivir)[c] • 3TC 150-mg/ZDV 300-mg tablet 3TC/DOR/TDF (Delstrigo) • 3TC 300-mg/DOR 100-mg/ TDF 300-mg tablet 3TC/DTG (Dovato) • 3TC 300-mg/DTG 50-mg tablet 3TC/ABC (Epzicom)[c]	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy *Dosing in Pregnancy* • No change in dose indicated For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, DOR, DTG, EFV, TDF, ZDV). Standard Adult Doses *3TC (Epivir)* • 3TC 150 mg twice daily or 300 mg once daily, without regard to food *3TC/TDF (Cimduo)* • One tablet once daily without regard to food *3TC/ZDV (Combivir)* • One tablet twice daily without regard to food *3TC/DOR/TDF (Delstrigo)* • One tablet once daily without regard to food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection. 3TC products that were developed specifically for treatment of HBV (e.g., Epivir-HBV) contain a lower dose of 3TC that is not appropriate for treatment of HIV.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Triumeq (3TC/ABC/DTG) *Triumeq PD* (3TC/ABC/ZDV) *Trizivir* Note: Generic products are available for some formulations.	• 3TC 300-mg/ABC 600-mg tablet 3TC/EFV/TDF (Symfi)[c] • 3TC 300-mg/EFV 600-mg/ TDF 300-mg tablet 3TC/EFV/TDF (Symfi Lo)[c] • 3TC 300-mg/EFV 400-mg/ TDF 300-mg tablet 3TC/TDF (Temixys) • 3TC 300-mg/TDF 300-mg tablet 3TC/ABC/DTG (Triumeq) • 3TC 300-mg/ABC 600-mg/ DTG 50-mg tablet 3TC/ABC/DTG (Triumeq PD) • Pediatric dispersible tablet: 3TC 30-mg/ABC 60-mg/ DTG 5-mg 3TC/ABC/ZDV (Trizivir)[c] • 3TC 150-mg/ABC 300-mg/ ZDV 300-mg tablet	*3TC/DTG (Dovato)* • One tablet once daily without regard to food *3TC/ABC (Epzicom)* • One tablet once daily without regard to food *3TC/EFV/TDF (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime *3TC/TDF (Temixys)* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq)* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq PD)* • Triumeq PD is a pediatric dispersible tablet not intended for use in adults; it is not recommended for use in patients weighing 25 kg or more. *3TC/ABC/ZDV (Trizivir)* • One tablet twice daily without regard to food		
Tenofovir Alafenamide (TAF)	TAF (Vemlidy)	Pregnancy	TAF: low placental transfer to fetus[b]	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Vemlidy (TAF/BIC/FTC) *Biktarvy* (TAF/FTC) *Descovy* (TAF/EVG/c/FTC) *Genvoya* (TAF/FTC/RPV) *Odefsey* (TAF/DRV/c/FTC) *Symtuza*	• 25-mg tablet TAF/BIC/FTC (Biktarvy) • TAF 25-mg/ BIC 50-mg/FTC 200-mg tablet TAF/FTC (Descovy) • TAF 25-mg/FTC 200-mg tablet TAF/EVG/c/FTC (Genvoya) • TAF 10-mg/EVG-150-mg/ COBI 150-mg/FTC 200-mg tablet TAF/FTC/RPV (Odefsey) • TAF 25-mg/FTC 200-mg/ RPV 25-mg tablet TAF/DRV/c/FTC (Symtuza) • TAF 10-mg/DRV 800-mg/ COBI 150-mg/FTC 200-mg tablet	*PK in Pregnancy* • AUC is lower in pregnancy, depending on the dose and concomitant ARV, but overall exposures are adequate. *Dosing in Pregnancy* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., BIC, COBI, DRV, EVG, FTC, RPV). Standard Adult Doses *TAF (Vemlidy)* • One tablet once daily with food *TAF/BIC/FTC (Biktarvy)* • One tablet once daily with or without food *TAF/FTC (Descovy)* • One tablet once daily with or without food • Same dose (TAF 25 mg) can be used with or without PK enhancers. *TAF/EVG/c/FTC (Genvoya)* • One tablet once daily with food *TAF/FTC/RPV (Odefsey)*	TFV: high placental transfer to fetus; plasma and cord blood concentrations lower than TDF[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) Renal function should be monitored because of the potential for renal toxicity.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		• One tablet once daily with food *TAF/DRV/c/FTC (Symtuza)* • One tablet once daily with food		
Tenofovir Disoproxil Fumarate (TDF) *Viread* (TDF/EFV/FTC) *Atripla* (TDF/3TC) *Cimduo* (TDF/FTC/RPV) *Complera* (TDF/DOR/3TC) *Delstrigo* (TDF/EVG/c/FTC) *Stribild* (TDF/EFV/3TC) *Symfi* (TDF/EFV/3TC) *Symfi Lo* (TDF/3TC) *Temixys* (TDF/FTC)	TDF (Viread) *Tablet*[c] • 300 mg *Powder* • 40-mg/1-g oral powder TDF/EFV/FTC (Atripla) • TDF 300-mg/EFV 600-mg/ FTC 200-mg tablet TDF/3TC (Cimduo) • TDF 300-mg/3TC 300-mg tablet TDF/FTC/RPV (Complera) • TDF 300-mg/FTC 200-mg/ RPV 25-mg tablet TDF/DOR/3TC (Delstrigo) • TDF 300-mg/DOR 100-mg/ 3TC 300-mg tablet TDF/EVG/c/FTC (Stribild)	Pregnancy *PK in Pregnancy* • AUC is lower in third trimester than postpartum, but trough levels are adequate. *Dosing in Pregnancy* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, COBI, DOR, EFV, EVG, FTC, RPV). Standard Adult Doses *TDF (Viread)* • Tablet o TDF 300 mg once daily without regard to food • Powder o TDF 8 mg/kg daily (up to a maximum of TDF 300 mg). Take with food. *TDF/EFV/FTC (Atripla)*	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) Human studies demonstrate no consistent link to LBW, but data are conflicting about potential effects on growth outcomes later in infancy. If patient has HBV/HIV coinfection, an HBV flare may occur if TDF is stopped; see Hepatitis B Virus/HIV Coinfection. Renal function should be monitored because of potential for renal toxicity.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Truvada Note: Generic products are available for some formulations.	• TDF 300-mg/EVG 150-mg/ COBI 150-mg/FTC 200-mg tablet TDF/EFV/3TC (Symfi) • TDF 300-mg/EFV 600-mg/ 3TC 300-mg tablet TDF/EFV/3TC (Symfi Lo) • TDF 300-mg/EFV 400-mg/ 3TC 300-mg tablet TDF/3TC (Temixys) • TDF 300-mg/3TC 300-mg tablet TDF/FTC (Truvada) • TDF 300-mg/FTC 200-mg tablet	• One tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects. *TDF/3TC (Cimduo)* • One tablet once daily without regard to food *TDF/FTC/RPV (Complera)* • One tablet once daily with food *TDF/DOR/3TC (Delstrigo)* • One tablet once daily without regard to food *TDF/EVG/c/FTC (Stribild)* • One tablet once daily with food *TDF/EFV/3TC (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime *TDF/3TC (Temixys)* • One tablet once daily without regard to food *TDF/FTC (Truvada)* • One tablet once daily without regard to food		
Zidovudine (ZDV) *Retrovir* (ZDV/3TC)	ZDV (Retrovir) *Capsule* • 100 mg	Pregnancy *PK in Pregnancy* • PK not significantly altered in pregnancy	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects)	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Combivir (ZDV/ABC/3TC) *Trizivir* Note: Generic products are available for all formulations.	*Tablet* • 300 mg *Oral Solution* • 10 mg/mL *IV Solution* • 10 mg/mL ZDV/3TC (Combivir) • ZDV 300-mg/3TC 150-mg tablet ZDV/ABC/3TC (Trizivir) • ZDV 300-mg/ABC 300-mg/3TC 150-mg tablet	*Dosing in Pregnancy* • No change in dose indicated • Patients in active labor should receive ZDV 2 mg/kg IV as a loading dose, followed by ZDV 1 mg/kg/hour continuous infusion from beginning of active labor until delivery. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC). Standard Adult Doses *ZDV (Retrovir)* • ZDV 300 mg twice daily or ZDV 200 mg three times a day without regard to food *ZDV/3TC (Combivir)* • One tablet twice daily without regard to food *ZDV/ABC/3TC (Trizivir)* • One tablet twice daily without regard to food		
NNRTIs NNRTIs interfere with HIV reverse transcriptase by binding directly to the enzyme.				
Doravirine (DOR) *Pifeltro* (DOR/3TC/TDF)	DOR (Pifeltro) • 100-mg tablet DOR/3TC/TDF (Delstrigo)	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy	No human *in vivo* data are available on the placental transfer of DOR, but passage is noted in *ex vivo* models.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Delstrigo	• DOR 100-mg/ 3TC 300-mg/ TDF 300-mg tablet	*Dosing in Pregnancy* • Insufficient data to make dosing recommendations For guidance about the use of combination ARV drug products in pregnancy, please see the specific sections on other drug components (i.e., 3TC, TDF). Standard Adult Doses *DOR (Pifeltro)* • DOR 100 mg once daily with or without food *DOR/3TC/TDF (Delstrigo)* • One tablet once daily with or without food	Insufficient data are available to assess for teratogenicity in humans. No evidence exists of teratogenicity in rats or rabbits.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Efavirenz (EFV) *Sustiva* (EFV/FTC/TDF) *Atripla* (EFV/3TC/TDF) *Symfi* (EFV/3TC/TDF) *Symfi Lo* Note: Generic products are available for some formulations.	EFV (Sustiva)[c] *Capsules* • 50 mg • 200 mg *Tablet* • 600 mg EFV/FTC/TDF (Atripla) • EFV 600-mg/FTC 200-mg/TDF 300-mg tablet EFV/3TC/TDF (Symfi) • EFV 600-mg/3TC 300-mg/TDF 300-mg tablet EFV/3TC/TDF (Symfi Lo) • EFV 400-mg/3TC 300-mg/TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • AUC is decreased during the third trimester compared with postpartum, but nearly all third-trimester participants exceeded target exposure. *Dosing in Pregnancy* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, FTC, TDF). Standard Adult Doses *EFV (Sustiva)* • EFV 600 mg once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/FTC/TDF (Atripla)* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/3TC/TDF (Symfi or Symfi Lo)* • One tablet once daily on an empty stomach and preferably at bedtime	Moderate placental transfer to fetus[b] The FDA advises women to avoid becoming pregnant while taking EFV and advises health care providers to avoid administration during the first trimester of pregnancy because fetal harm may occur. However, the data on more than 7,900 periconception EFV exposures from Botswana rule out a threefold or greater increased risk of NTDs. As a result, the current Perinatal Guidelines do not restrict the use of EFV in pregnant women or in women who are planning to become pregnant. This is consistent with both the British HIV Association and WHO guidelines for use of ARV drugs in pregnancy. EFV should be continued in pregnant women who are on a virally suppressive, EFV-based regimen, because ARV drug changes during pregnancy may be associated with loss of viral control and an increased risk of perinatal transmission (see People with HIV Who Are Taking Antiretroviral Therapy When They Become Pregnant).	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Etravirine (ETR) *Intelence*	Tablet • 25 mg • 100 mg • 200 mg For patients who are unable to swallow tablets whole, the tablets may be dissolved in a glass of water.	Pregnancy *PK in Pregnancy* • PK data in pregnancy suggest 1.2-fold to 1.6-fold increases in ETR exposure during pregnancy. *Dosing in Pregnancy* • No change in dose is indicated. Standard Adult Doses • 200 mg twice daily with food	Placental transfer varies; it is usually in the moderate-to-high category, ranging from 0.19 to 4.25.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024
Nevirapine (NVP) Viramune Viramune XR Note: Generic products are available for some formulations.	NVP (Viramune) *Tablet* • 200 mg[c] *Oral Suspension* • 50 mg/5 mL[c] Viramune XR *Tablets* • 100 mg • 400 mg[c]	Pregnancy *PK in Pregnancy* • PK of immediate-release tablets not significantly altered in pregnancy • No data available on extended-release formulations in pregnancy *Dosing in Pregnancy* • No change in dose indicated Standard Adult Doses • NVP 200 mg once daily (using Viramune immediate release) for a 14-day lead-in period; thereafter, NVP 200 mg twice daily or 400 mg (using Viramune XR tablet) once daily, without regard to food • Repeat the lead-in period if therapy is discontinued for >7 days.	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects and 2-fold increase in cardiovascular and genitourinary defects) An increased risk of symptomatic liver toxicity exists when first initiating therapy in women with CD4 counts ≥250/mm^3. Liver toxicity is often associated with a rash and can be fatal. Pregnancy does not appear to increase this risk. NVP should be initiated in pregnant people with CD4 counts ≥250 cells/mm^3 only if benefit clearly outweighs risk. A potential increased risk of life-threatening hepatotoxicity exists in pregnant people with high CD4 counts. Elevated	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		• In patients who develop mild-to-moderate rash without constitutional symptoms during the lead-in period, continue lead-in dosing until rash resolves, but administer for ≤28 days total.	transaminase levels at baseline may increase the risk of NVP toxicity. Patients who become pregnant while taking NVP-containing regimens and who are tolerating their regimens well can continue taking those regimens, regardless of their CD4 counts.	
Rilpivirine (RPV) *Edurant* (RPV/FTC/TDF) *Complera* (RPV/DTG) *Juluca* (RPV/FTC/TAF) *Odefsey* (CAB and RPV) *Cabenuva* CAB and RPV is a two-drug co-packaged product for IM injection.	RPV (Edurant) *Tablets* • 25 mg RPV/FTC/TDF (Complera) • RPV 25-mg/ FTC 200-mg/ TDF 300-mg tablet RPV/DTG (Juluca) • RPV 25-mg/DTG 50-mg tablet RPV/FTC/TAF (Odefsey) • RPV 25-mg/FTC 200-mg/ TAF 25-mg tablet CAB and RPV (Cabenuva) • CAB 200-mg/mL suspension for IM injection • RPV 300-mg/mL suspension for IM injection	Pregnancy *PK in Pregnancy* • RPV PK are highly variable during pregnancy. RPV AUC and trough concentrations are 20% to 50% lower in pregnancy than postpartum. Although most pregnant women exceeded target exposure, those with detectable viral loads had lower RPV troughs. *Dosing in Pregnancy* • Although RPV plasma concentration is reduced during pregnancy, higher-than-standard doses have not been studied, and not enough data are available to recommend a dosing change during pregnancy. Pregnant people receiving standard dosing should have their viral loads monitored more frequently than people who are not receiving RPV. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., CAB, DT G, FTC, TAF, TDF). Standard Adult Doses	Moderate-to-high placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) Two-drug regimens (e.g., the RPV/DTG FDC) are not recommended for use in pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		RPV (Edurant) • RPV 25 mg once daily with food *RPV/FTC/TDF (Complera)* • One tablet once daily with food *RPV/DTG (Juluca)* • One tablet once daily with food *RPV/FTC/TAF (Odefsey)* • One tablet once daily with food *CAB and RPV (Cabenuva)* • Refer to Cabotegravir for dosing and instructions.		
PIs PIs block the activity of the protease enzyme, which is required to assemble new HIV viral particles that are capable of infecting new cells.				
Atazanavir (ATV) *Reyataz* Note: Generic products are available for some formulations. Note: ATV must be combined with low-dose RTV boosting in pregnancy. (ATV/c)	ATV (Reyataz) *Capsules* • 100 mg (generic product only) • 150 mg[c] (generic product only) • 200 mg[c] • 300 mg[c] *Oral Powder* • 50-mg packet	Pregnancy *PK in Pregnancy* • ATV (Reyataz) o ATV concentrations are reduced during pregnancy, and they are further reduced when ATV is given concomitantly with TDF or an H2-receptor antagonist. o Intracellular ATV levels in women taking the standard dose (ATV/r 300 mg/100 mg) without	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) Must be given with RTV boosting in pregnancy Effect of *in utero* ATV exposure on infant indirect bilirubin levels is unclear. Nonpathologic elevations of neonatal	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Evotaz	ATV/c (Evotaz) • ATV 300-mg/COBI 150-mg tablet	concomitant TDF appear reassuringly stable throughout pregnancy. • ATV/c (Evotaz) o Use of ATV/c **is not recommended** during pregnancy because ATV trough concentrations are 80% to 85% lower than the ATV concentrations seen in nonpregnant adults. *Dosing in Pregnancy* • ATV (Reyataz) o Use of unboosted ATV **is not recommended** during pregnancy. o Use of unboosted ATV **is not recommended** during pregnancy for ARV-experienced patients who are taking TDF and an H2-receptor antagonist. o Use of an increased dose (ATV/r 400 mg/100 mg once daily with food) during the second and third trimesters results in plasma ATV concentrations equivalent to those seen in nonpregnant adults receiving standard dosing. Increased ATV dosing is recommended for pregnant people in the second and third trimesters who are also receiving either TDF or an H2-receptor antagonist. • ATV/c (Evotaz) o ATV/c should not be used in pregnancy because atazanavir C_{min} is substantially reduced (see COBI).	bilirubin have been observed in some, but not all, clinical trials to date. Oral powder (but **not** capsules) contains phenylalanine, which can be harmful to patients with phenylketonuria. Use of ATV/c **is not recommended** during pregnancy. See Recommendations for Use of Antiretroviral Drugs During Pregnancy, Table 6, and Table 7 for discussions about avoiding the use of ATV/c during pregnancy.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		For guidance about the use of combination products in pregnancy, see the specific sections on other components (i.e., COBI). Standard Adult Doses *In ARV-Naive Patients without RTV Boosting* • ATV 400 mg once daily with food; ATV without RTV boosting **is not recommended** when used with TDF, H2-receptor antagonists, PPIs, or during pregnancy. *In ARV-Naive Patients with RTV Boosting* • ATV/r 300 mg/100 mg once daily with food • When combined with EFV in ARV-naive patients: ATV/r 400 mg/100 mg once daily with food *In ARV-Experienced Patients* • ATV 300 mg plus RTV 100 mg once daily with food • **Do not use** with PPIs or EFV. *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist* • ATV/r 300/100 mg once daily with food *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist and TDF* • ATV/r 400 mg/100 mg once daily with food		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Powder Formulation • Oral powder is taken with RTV once daily with food at the same recommended adult dose as the capsules. *ATV/c (Evotaz)* • One tablet once daily with food		
Darunavir (DRV) *Prezista* Note: Must be combined with low-dose RTV or COBI boosting. (DRV/c) *Prezcobix* (DRV/c/FTC/TAF) *Symtuza*	DRV (Prezista) *Tablet* • 75 mg • 150 mg • 600 mg • 800 mg *Oral Suspension* • 100 mg/mL DRV/c (Prezcobix) • DRV/c 800-mg/ 150-mg tablet DRV/c/FTC/TAF (Symtuza) • DRV 800-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet	Pregnancy *PK in Pregnancy* • Decreased exposure in pregnancy with use of DRV/r *Dosing in Pregnancy* • The Panel does not recommend once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. • Twice-daily DRV/r dosing (DRV/r 600 mg/100 mg with food) is recommended for all pregnant people. • Increased twice-daily DRV dose (DRV/r 800 mg/100 mg with food) during pregnancy does not result in an increase in DRV exposure and is not recommended. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF). Standard Adult Doses *ARV-Naive Patients*	Low placental transfer to fetus[b] No evidence of teratogenicity in mice, rats, or rabbits. No evidence of human teratogenicity. Must be boosted with low-dose RTV The Panel does not recommend once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. If a DRV/c regimen is continued during pregnancy, viral load should be monitored frequently.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		• DRV/r 800 mg/100 mg once daily with food • DRV/c 800 mg/150 mg once daily with food *ARV-Experienced Patients If Patient Has No DRV Resistance Mutations* • DRV/r 800 mg/100 mg once daily with food • DRV/c 800 mg/150 mg once daily with food *ARV-Experienced Patients If Any DRV Resistance Mutations Are Present* • DRV/r 600 mg/100 mg twice daily with food *DRV/c (Prezcobix)* • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza)* • One tablet once daily with food		
Lopinavir/Ritonavir (LPV/r) *Kaletra* Note: Generic products are available for all formulations.	LPV/r (Kaletra)[c] *Tablets* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution* • Each 5 mL contains LPV/r 400 mg/100 mg.	Pregnancy *PK in Pregnancy* • With twice-daily dosing, LPV exposure is reduced in pregnant women who receive standard adult doses, increasing the dose by 50% results in exposure equivalent to that seen in nonpregnant adults receiving standard doses. • No PK data are available for once-daily dosing in pregnancy.	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) Oral solution contains 42% alcohol and 15% propylene glycol and is not recommended for use in pregnancy. Once-daily LPV/r dosing is not recommended during pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Dosing in Pregnancy • Once-daily dosing is not recommended during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters, especially in PI-experienced pregnant women and women who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels. Standard Adult Doses • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/20 mg once daily *Tablets* • Take without regard to food. *Oral Solution* • Take with a meal. *With EFV or NVP in PI-Naive or PI-Experienced Patients* • LPV/r 500-mg/125-mg tablets twice daily without regard to meals (use a combination of two LPV/r		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		200-mg/50-mg tablets and one LPV/r 100-mg/25-mg tablet), *or* • LPV/r 520-mg/130-mg oral solution (6.5 mL) twice daily with food		
Entry Inhibitors Entry and attachment inhibitors block viral binding or fusion of HIV to host cells.				
Fostemsavir (FTR) *Rukobia*	• Extended-release tablet: 600 mg	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendation Standard Adult Doses *(FTR) Rukobia* • FTR 600 mg twice daily with or without food	No human data are available regarding placental passage. A study in rats demonstrates placental passage of temsavir or other metabolites. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024
Ibalizumab-uiyk (IBA) *Trogarzo*	IV Solution • 150 mg/mL	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations	No human data are available, but placental transfer of IBA, a monoclonal antibody, is possible and documented in monkeys. Based on data in cynomolgus monkeys with *in utero* exposure, the potential exists for reversible immunosuppression (CD4 T cell and B cell lymphocytopenia) in infants born to mothers exposed to IBA during pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Standard Adult Doses • IBA 2,000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks	The FDA requires collection of prospective data in individuals exposed to IBA during pregnancy to monitor maternal and pregnancy outcomes, including adverse effects on the developing fetus, neonate, and infant. Insufficient data to assess for teratogenicity in humans	
Maraviroc (MVC) *Selzentry*	Tablets • 150 mg • 300 mg	Pregnancy *PK in Pregnancy* • A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in MVC AUC, but C_{trough} exceeded the recommended minimum concentration of 50 ng/mL. *Dosing in Pregnancy* • Adjusting the standard adult MVC dose for concomitant use with ARV drugs seems appropriate. Standard Adult Doses • MVC 300 mg twice daily with or without food • MVC should be used only for patients with CCR5-tropic virus (and no X4-tropic virus). *Dose Adjustments* • Increase to MVC 600 mg twice daily when used with the potent CYP3A inducers EFV, ETR, and rifampin	Moderate placental transfer to fetus[b] No evidence of teratogenicity in rats or rabbits; insufficient data to assess teratogenicity in humans	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		• Decrease to MVC 150 mg twice daily when used with CYP3A inhibitors, which include all PIs except TPV/r and itraconazole		
Capsid Inhibitor Capsid inhibitors are a class of drugs that interfere with HIV capsid, a protein shell that protects HIV's genetic material and enzymes needed for replication. Capsid inhibitors can disrupt HIV capsid during multiple stages of the viral life cycle.				
Lenacapavir (LEN) *Sunlenca*	LEN (Sunlenca) • LEN 300-mg tablets for oral administration • LEN 463.5 mg/1.5 ml for SQ injection	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendations Standard Adult Doses *Initiation Option 1* • Day 1: 927 mg by SQ injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300-mg tablets) • Day 2: 600 mg orally (2 x 300-mg tablets). *Initiation Option 2* • Day 1: 600 mg orally (2 x 300-mg tablets) • Day 2: 600 mg orally (2 x 300-mg tablets) • Day 8: 300 mg orally (1 x 300-mg tablet) • Day 15: 927 mg by SQ injection (2 x 1.5 mL injections)	No human data are available regarding placental passage or through breast milk. Data are insufficient to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		Maintenance Dosing • 927 mg by SQ injection (2 x 1.5 mL injections) every 26 weeks +/- 2 weeks from date of last injection		
INSTIs INSTIs are the viral enzyme that catalyzes the two-step process that inserts HIV DNA into the genome of the host cell.				
Bictegravir/Emtricitabine/ Tenofovir Alafenamide (BIC/FTC/TAF) *Biktarvy* Note: BIC is available only as part of an FDC tablet.	BIC/FTC/TAF (Biktarvy) • BIC 50-mg/FTC 200 mg/ TAF 25-mg tablet • BIC 30-mg/FTC 120-mg/ TAF 15-mg tablet	Pregnancy *PK in Pregnancy* • AUC and C_{24h}/C_{trough} are decreased during the third trimester compared with postpartum, but exposures during pregnancy are well above those needed to inhibit viral replication. *Dosing in Pregnancy* • No change in dose indicated For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF). Standard Adult Doses • One tablet of BIC 50 mg/FTC 200 mg/TAF 25 mg once daily with or without food	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects) BIC can be taken with food at the same time as any preparation containing iron or calcium—including prenatal vitamins—but should not be administered within 2 hours of these preparations when taken on an empty stomach. BIC can be taken at least 2 hours before or 6 hours after antacids containing aluminum or magnesium.	January 31, 2024
Cabotegravir (CAB) *Vocabria (oral)* *Apretude (injection for HIV pre-exposure prophylaxis)* (CAB)	CAB • CAB 30-mg tablets for oral administration • CAB 200-mg/mL suspension for IM injection	Pregnancy *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy*	No human data are available regarding placental passage. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Cabenuva Note: CAB and RPV is a two-drug co-packaged product for IM injection.	CAB and RPV • CAB 200-mg/mL suspension for IM injection • RPV 300-mg/mL suspension for IM injection	• Insufficient data to make dosing recommendations For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., RPV). Standard Adult Doses *Oral Lead-In Therapy (Optional)* • CAB (Vocabria) o One 30-mg tablet once daily in combination with RPV (Edurant) 25-mg once daily taken with a meal for 4 weeks • CAB (Apretude) o Initiation ▪ CAB 600-mg (3 mL) injections given 1 month apart for 2 consecutive months (on the last day of an oral lead-in, if used, or within 3 days) o Continuation Therapy ▪ CAB 600-mg (3 mL) injections every 2 months thereafter • CAB and RPV (Cabenuva) o Initiation ▪ CAB 600-mg (3 mL) and RPV 900-mg (3 mL), given as two separate injections in separate ventrogluteal sites for 2 consecutive months (on the last day of an oral lead-in if used) o Continuation Therapy		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		▪ *Monthly:* CAB 400-mg (2 mL) and RPV 600-mg (2 mL), given as two separate injections in separate ventrogluteal sites once a month with allowance for a +/- 7-day administration window ▪ *Every 2 months:* Starting in month 4, CAB 600-mg (2 mL) and RPV 900-mg (2 mL), given as two separate injections in separate ventrogluteal sites once a month with allowance for a +/- 7-day administration window ▪ Patients should be monitored for approximately 10 minutes for post-injection reactions. A 23-gauge, 1.5-inch IM needle is recommended for the injection and is provided in the packaging. Longer, 2-inch needles should be used in patients with BMIs >30 kg/m^2. *Changing Dosing Frequency and Managing Missed Doses* • Refer to the package insert for instructions about changing the frequency of continuation doses and managing missed doses (see Apretude and Cabenuva).		
Dolutegravir (DTG) *Tivicay* *Tivicay PD* (DTG/3TC) *Dovato*	DTG (Tivicay) • DTG 10-mg, 25-mg, and 50-mg film-coated tablets DTG (Tivicay PD)	Pregnancy *PK in Pregnancy* • AUC may be decreased during the third trimester compared with postpartum, but exposures during	High placental transfer to fetus[b] No evidence of teratogenicity in rats or rabbits. The most recent data from Botswana indicate the prevalence of NTDs in infants born to pregnant women with HIV receiving DTG at conception is no	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(DTG/RPV) *Juluca* (DTG/ABC/3TC) *Triumeq*	• DTG 5-mg dispersible tablet for oral suspension DTG film-coated tablets and DTG dispersible tablets are not bioequivalent and are not interchangeable. DTG/3TC (Dovato) • DTG 50-mg/3TC 300-mg tablet DTG/RPV (Juluca) • DTG 50-mg/RPV 25-mg tablet DTG/ABC/3TC (Triumeq) • DTG 50-mg/ABC 600-mg/ 3TC 300-mg tablet	pregnancy are well above those needed to inhibit viral replication. *Dosing in Pregnancy* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC, RPV). Standard Adult Doses *In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients* • DTG (Tivicay) o One 50-mg tablet once daily, without regard to food • DTG (Tivicay PD) o Six 5-mg tablets (30 mg) dissolved in water once daily, without regard to food • DTG/3TC (Dovato) o One tablet once daily, without regard to food • DTG/RPV (Juluca) o One tablet once daily, with food • DTG/ABC/3TC (Triumeq) o One tablet once daily, without regard to food	longer statistically different than in those receiving other antiretrovirals. DTG is a *Preferred* antiretroviral drug for use during pregnancy, irrespective of trimester, and for people who are trying to conceive (see Recommendations for Use of Antiretroviral Drugs During Pregnancy and Table 7). To maximize DTG absorption, doses should not be administered within 2 hours of ingesting any preparation that contains such minerals as iron or calcium, including prenatal vitamins.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients Who Are Also Receiving EFV, FPV/r, TPV/r, or Rifampin • DTG (Tivicay) o One 50-mg tablet twice daily, without regard to food • DTG (Tivicay PD) o Six 5-mg tablets (30 mg) dissolved in water twice daily, without regard to food *In INSTI-Experienced Patients* • DTG (Tivicay) o One tablet twice daily, without regard to food		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
Elvitegravir (EVG) Note: As of October 2017, the single-drug formulation of EVG (Vitekta) is no longer available. (EVG/c/FTC/TAF) *Genvoya* (EVG/c/FTC/TDF) *Stribild*	EVG/c/FTC/TAF (Genvoya) • EVG 150-mg/COBI 150-mg/FTC 200-mg/TAF 10-mg tablet EVG/c/FTC/TDF (Stribild) • EVG 150-mg/COBI 150-mg/FTC 200-mg/ TDF 300-mg tablet	Pregnancy *PK in Pregnancy* • PK studies in women who received EVG/c demonstrated significant reduction in EVG plasma exposure during pregnancy. *Dosing in Pregnancy* • EVG plasma concentrations are reduced with use of standard adult doses during pregnancy; however, higher-than-standard doses of EVG have not been studied. Insufficient data are available to recommend a dose for use in pregnancy. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF). Standard Adult Doses *Genvoya and Stribild* • One tablet once daily with food	Evidence of high placental transfer of EVG and low transfer of COBI[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. EVG/c is not recommended for use in pregnancy. For persons who become pregnant while taking EVG/c, consider frequent viral load monitoring or switching to a more effective, recommended regimen. If a pregnant person continues taking a regimen that contains EVG/c, doses should be administered with a meal and should not be administered within 2 hours of ingesting any preparation that contains minerals, such as iron or calcium, including prenatal vitamins.	January 31, 2024
Raltegravir (RAL) *Isentress* *Isentress HD*	RAL (Isentress) *Film-Coated Tablets* • 400 mg *Chewable Tablets* • 25 mg • 100 mg	Pregnancy *PK in Pregnancy* • Decreased drug concentrations in the third trimester are not of sufficient magnitude to warrant a change in dosing. *Dosing in Pregnancy* • No change in dose is indicated.	High placental transfer to fetus[b] No evidence of human teratogenicity (can rule out a 1.5-fold increase in overall birth defects) There is a case report of markedly elevated liver transaminases with RAL use in late pregnancy. Severe, potentially life-threatening, and fatal skin reactions and	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
	RAL (Isentress HD) *Film-Coated Tablets* • 600 mg	• Once-daily dosing (i.e., two RAL 600-mg film-coated tablets) should not be used in pregnant individuals until more information is available. Standard Adult Doses *In Patients Who Are Not Receiving Rifampin* • RAL 400-mg film-coated tablets twice daily without regard to food • Two RAL 600-mg film-coated tablets (1,200 mg) once daily without regard to food for ARV-naive patients or patients who are already virologically suppressed on an initial regimen of RAL 400 mg twice daily • Chewable tablets and oral suspension doses are not interchangeable with either film-coated tablets or each other. *In Patients Who Are Receiving Rifampin* • Two RAL 400-mg film-coated tablets (800 mg) twice daily without regard to food	HSRs have been reported in nonpregnant adults. RAL chewable tablets contain phenylalanine. To maximize RAL absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals—such as iron or calcium—including prenatal vitamins.	
Pharmacoenhancers Pharmacoenhancers reduce the metabolism of antiretroviral drugs and prolong their presence in plasma, allowing for more convenient dosing regimens.				
Cobicistat (COBI) *Tybost* (ATV/c) *Evotaz*	COBI (Tybost) *Tablet* • COBI 150 mg ATV/c (Evotaz)	Pregnancy *PK in Pregnancy* • Based on limited data, COBI exposure and its pharmaco-enhancing effect on ATV, DRV, and EVG are reduced markedly in pregnancy.	Low placental transfer to fetus[b] No evidence of human teratogenicity (can rule out twofold increase in overall birth defects)	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
(EVG/c/FTC/TAF) *Genvoya* (DRV/c) *Prezcobix* (EVG/c/FTC/TDF) *Stribild* (DRV/c/FTC/TAF) Symtuza	• ATV 300-mg/ COBI 50-mg tablet EVG/c/FTC/TAF (Genvoya) • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet DRV/c (Prezcobix) • DRV 800-mg/ COBI 150-mg tablet EVG/c/FTC/TDF (Stribild) • EVG 150-mg/ COBI 150-mg/ FTC 200-mg/ TDF 300-mg tablet DRV/c/FTC/TAF (Symtuza) • DRV 800-mg/ COBI 150-mg/ FTC 200-mg/ TAF 10-mg tablet	• When coadministered with COBI, TAF exposure is not significantly different between pregnancy and the postpartum period. *Dosing in Pregnancy* • Although COBI exposure is reduced markedly during pregnancy, higher-than-standard doses have not been studied. The Panel recommends RTV as the preferred pharmaco-enhancer for PIs and INSTIs during pregnancy until more data are available on COBI activity during pregnancy. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF, TDF, ATV, DRV, EVG). Standard Adult Doses *COBI (Tybost)* • When used as an alternative PK booster with ATV or DRV, the dose is one tablet once daily with food. *ATV/c (Evotaz)* • One tablet once daily with food *EVG/c/FTC/TAF (Genvoya)* • One tablet once daily with food *DRV/c (Prezcobix)* • One tablet once daily with food	Use of COBI-boosted ATV, DRV, or EVG is not recommended in pregnancy.	

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		EVG/c/FTC/TDF (Stribild) • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza)* • One tablet once daily with food		
Ritonavir (RTV) *Norvir* (LPV/r) *Kaletra*	RTV (Norvir) *Capsule* • RTV 100 mg *Tablet* • RTV 100 mg *Oral Solution* • RTV 80 mg/mL *Powder* • RTV 100 mg/sachet LPV/r (Kaletra) *Tablets* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution* • Each 5 mL contains LPV/r 400 mg/100 mg.	Pregnancy *PK in Pregnancy* • Lower RTV levels are seen during pregnancy than during postpartum, which may reduce the pharmaco-enhancing effect of RTV in pregnancy. *RTV Dosing in Pregnancy* • No dose adjustment is necessary when RTV is used as booster. *LPV/r Dosing in Pregnancy* • Once-daily dosing is not recommended during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/ 150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters of pregnancy, especially in patients who are PI-experienced and in those who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels.	Low placental transfer to fetus[b] No evidence of increased risk of human teratogenicity (can rule out 1.5-fold increase in overall birth defects) RTV should only be used as a low-dose booster for other PIs. RTV oral solution contains 43% alcohol and, therefore, is not recommended for use during pregnancy because no safe level of alcohol exposure during pregnancy is known. LPV/r oral solution contains 42% alcohol and 15% propylene glycol and is not recommended for use in pregnancy. Once-daily LPV/r dosing is not recommended during pregnancy.	January 31, 2024

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., LPV/r). Standard Adult Dose of RTV (Norvir) When Used as a PK Booster for Other PIs • RTV 100–400 mg per day in one or two divided doses (refer to other PI sections for specific dosing recommendations). *Tablet* • Take with food. *Capsule or Oral Solution* • To improve tolerability, take with food, if possible. Standard Adult Doses of LPV/r (Kaletra) • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/200 mg once daily *Tablet* • Take without regard to food. *Oral Solution* • Take with food.		

Table 14. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy	Last Reviewed
		With EFV or NVP in PI-Naive or PI-Experienced Patients • LPV/r 500-mg/125-mg tablets twice daily without regard to meals (use a combination of two LPV/r 200-mg/50-mg tablets and one LPV/r 100-mg/25-mg tablet), *or* • LPV/r 520-mg/130-mg oral solution (6.5 mL) twice daily with food		

[a] Individual ARV drug doses may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Antiretroviral Guidelines, Appendix B, Table 12).

[b] Placental transfer categories are determined by mean or median cord blood–to–maternal delivery plasma drug ratio:

High: >0.6
Moderate: 0.3–0.6
Low: <0.3

[c] Generic product available

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; AUC = area under the curve; BIC = bictegravir; BMI = body mass index; C_{24h} = concentrations at 24 hours postdose; CAB = cabotegravir; CD4 = CD4 T lymphocyte; COBI = cobicistat; CYP = cytochrome P; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; FTR = fostemsavir; HBV = hepatitis b virus; HSR = hypersensitivity reaction; IBA = ibalizumab; IM = intramuscular; INSTI = integrase strand transfer inhibitor; IV = intravenous; LEN = lenacapavir; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NTD = neural tube defect; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; PPI = proton pump inhibitor; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQ = subcutaneous; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; WHO = World Health Organization; ZDV = zidovudine