PRE-EXPOSURE PROPHYLAXIS (PREP) TO PREVENT HIV DURING PERICONCEPTION, ANTEPARTUM, AND POSTPARTUM PERIODS

Updated: March 31, 2026
Reviewed: March 31, 2026

Panel's Recommendations
• Health care professionals should discuss HIV pre-exposure prophylaxis (PrEP) with all sexually active people without HIV, including those who are trying to conceive, pregnant, postpartum, or breastfeeding, to prevent HIV acquisition **(AII).** Counseling should include the benefits of PrEP to prevent HIV acquisition and perinatal transmission **(AI)** and potential adverse effects of PrEP during periconception, pregnancy, and postpartum/breastfeeding **(AII).** Health care professionals should offer PrEP to those who desire PrEP or have specific indications for PrEP **(AII).** • There are several U.S. Food and Drug Administration–approved PrEP options for preventing HIV transmission from receptive vaginal sex, including during pregnancy and breastfeeding; health care professionals should discuss potential options with patients and engage in shared decision-making to assist in choosing the best HIV prevention option for the individual patient **(AIII).** o Tenofovir disoproxil fumarate plus emtricitabine is recommended for PrEP during pregnancy and breastfeeding as a daily oral product with robust safety and pharmacokinetic data during pregnancy and postpartum/breastfeeding **(AII).** o Lenacapavir is recommended for PrEP during pregnancy and breastfeeding as an injectable product given subcutaneously every 6 months that is highly effective for vaginal exposure to HIV and for which there is evidence for efficacy and safety during pregnancy and breastfeeding **(AI).** o Cabotegravir (CAB) can be considered for PrEP during pregnancy and breastfeeding as an injectable PrEP product given intramuscularly every 2 months that is highly effective for vaginal exposure to HIV, with emerging data to suggest that CAB is effective and safe during pregnancy and breastfeeding **(BII).** • Episodic or nondaily PrEP **is not recommended** for protection against vaginal exposure to HIV **(AIII).** • Risk for HIV acquisition should be regularly reassessed and patients should be counseled regarding the benefits and risks of HIV prevention options in pregnancy and breastfeeding **(AII).** • If pregnancy occurs while receiving PrEP or if PrEP is initiated during pregnancy, clinicians are strongly encouraged to register the pregnancy with the Antiretroviral Pregnancy Registry **(AIII)** (see Teratogenicity). • Health care professionals should offer routine PrEP follow-up, including HIV testing and counseling on signs and symptoms of acute retroviral syndrome **(AI)** (see Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure and the Centers for Disease Control and Prevention's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline and Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis—United States, 2025). Consider more frequent testing when clinically indicated (e.g., adherence challenges, nonstandard visit schedule).
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*

HIV pre-exposure prophylaxis (PrEP) is the use of specific antiretroviral (ARV) drugs to prevent HIV acquisition. Susceptibility to HIV acquisition may be greater during the periconception period, throughout pregnancy, and through 6 months postpartum. Acute or recent HIV infection during pregnancy or breastfeeding is associated with an increased risk of perinatal HIV transmission (see Early [Acute and Recent] HIV Infection).[1,2] The Panel on Treatment of HIV Infection During Pregnancy and Prevention of Perinatal Transmission (the Panel) recommends counseling about PrEP for HIV prevention and offering PrEP (or referred for PrEP services) to prevent HIV acquisition and potential secondary or perinatal HIV transmission when patients without HIV are planning to have a child or are pregnant, postpartum, or breastfeeding.[3]

Combination tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) as daily oral PrEP to reduce HIV acquisition was approved by the U.S. Food and Drug Administration (FDA) in 2012. In 2021 and 2025, the FDA approved as PrEP long-acting injectable cabotegravir (CAB-LA) administered every 2 months intramuscularly and long-acting injectable lenacapavir (LEN) administered every 6 months subcutaneously, respectively. All three products are endorsed by the Centers for Disease Control and Prevention (CDC) and approved by the FDA for use during pregnancy and breastfeeding to prevent HIV acquisition through vaginal exposure.[4,5]

All three of these agents are highly efficacious in preventing HIV. Due to the durations during which the products have been on the market as HIV treatment and prevention, TDF/FTC has the most robust published safety data during pregnancy, early postpartum, and breastfeeding, followed by LEN. Data on CAB-LA use during pregnancy and breastfeeding are emerging. Both preliminary and published data are reassuring, and offering choices in PrEP modality may increase PrEP utilization among those with potential exposure to HIV.[4,6,7] Non-oral options may be especially relevant during pregnancy, when nausea and vomiting associated with pregnancy can further impede adherence to oral medications. The Panel recommends offering comprehensive education and counseling on PrEP options for the periconception, pregnancy, and postpartum periods and provision of PrEP services during these critically important time periods for HIV prevention.

Background on HIV Susceptibility During Periconception, Antepartum, and Postpartum Periods

Susceptibility to HIV acquisition may be greater during periconception, antepartum, and early postpartum periods through 6 months. Data suggest that there is a higher risk for HIV acquisition while trying to conceive, likely due to increased condomless sex.[8-13] The increase in HIV acquisition risk continues in pregnancy and is likely due to a combination of behavioral factors—such as no longer needing to use condoms for contraception—and biological factors that include increased innate and suppressed adaptive immunity, increased genital tract inflammation, alterations in the vaginal microbiome, decreased integrity of the vaginal epithelium, and both gross trauma and microtrauma to the genital tract during birth.[14-16] HIV incidence among women during pregnancy and postpartum is two to six times greater than HIV incidence outside of pregnancy.[11,16-19] Two large HIV prevention studies conducted in African countries demonstrated that the probability of HIV acquisition per condomless sex act increases beginning in early pregnancy and peaks in the early postpartum period (in data analyzed from birth through 24 weeks postpartum in most studies). After adjustment for age, use of PrEP, and male partner HIV viral load, the probability of HIV acquisition was significantly higher throughout pregnancy and the postpartum period (adjusted relative risk 2.76; 95% confidence interval [CI], 1.58–4.81).[20] In addition, when HIV is acquired while pregnant or breastfeeding, compared to HIV acquired before pregnancy/breastfeeding, there is a greater likelihood of transmitting HIV to infants.[10,21,22]

Clinical Management of PrEP Use During Periconception, Antepartum, and Postpartum Periods

Initiating PrEP

The CDC provides guidelines (see Clinical Guidance for PrEP and Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis—United States, 2025) for discussing PrEP with all adults and adolescents who have sex or inject drugs.[3] To address underutilization of PrEP and disparities in PrEP use among women,[23,24] it is important for clinicians and clinical programs to consider strategies such as health care professional education, standard protocols, clinic champions, and resource tools to optimize implementation and reduce barriers to accessing PrEP.[25-29] PrEP can be prescribed to any individuals who request it and is also specifically recommended for individuals with clinical indications. See CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline for further details.

When prescribing PrEP in the periconception, antepartum, or postpartum period, clinicians should—

- Confirm that no acute, potential exposure to HIV has occurred in the past 72 hours. In such cases, nonoccupational postexposure prophylaxis should be administered for 28 days prior to initiating PrEP.[30]
- Counsel about potential risks and benefits of PrEP and all available strategies for reducing HIV acquisition risks during periconception, antepartum, and postpartum periods (see Reproductive Options When One or Both Partners Have HIV). If pregnancy occurs while using oral or injectable PrEP, PrEP use can continue throughout pregnancy.
- Counsel that condomless sex with a partner who has sustained viral suppression is associated with virtually no risk of HIV sexual transmission (see Reproductive Options When One or Both Partners Have HIV).[31-34]
- Explain how long PrEP needs to be taken in order to be protected from vaginal HIV exposure.
    - Daily oral TDF/FTC must be taken for at least 20 days before drug levels are high in cervicovaginal tissues. Therefore, the Panel recommends 20 days of oral PrEP before determining full protection from HIV acquisition via vaginal exposure.
    - For cabotegravir (CAB), 7 days is the estimated time to protection.
    - For LEN, subcutaneous LEN is administered as an initial injection accompanied by an oral loading dose of LEN tablets daily on Days 1 and 2, followed by maintenance injections every 6 months. Patients are expected to achieve protective levels of drug within 2 hours after the dose on Day 2 if both days of oral loading are taken. If both days of oral loading are missed, that time to protection increases to an estimated 21–28 days. (See Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis—United States, 2025).
- Counsel about the importance of adherence to daily pills or follow-up visits for injections and suggest adherence supports (see Adherence Support below).
- Counsel that episodic, "2-1-1," "on-demand," and/or nondaily oral PrEP has not been evaluated for protection against vaginal HIV exposure and **is not recommended**.

- When PrEP is used, counsel about the symptoms associated with acute HIV infection and recommend contacting a health care professional immediately for HIV testing and further evaluation if symptoms occur (see Early [Acute and Recent] HIV Infection). If symptoms of acute HIV infection occur, advise to use a condom during sex, stop attempts at conception, and stop breastfeeding.
- Explain that PrEP does not protect against other sexually transmitted infections (STIs). Condom use is important for reducing STI acquisition.
- Regularly assess and discuss ongoing needs for PrEP.
- Inquire about partner status and offer partner HIV testing.
- Additional prescribing details, including for same-day oral PrEP start and oral PrEP follow-up via telehealth, are offered in the CDC Guidelines for PrEP (see Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline).[3]
- If a patient receiving PrEP becomes pregnant, the available safety data, including the long half-life of long-acting injectable PrEP drugs, should be discussed. The patient and health care professionals should engage in shared decision-making about HIV prevention options in pregnancy. Expert consultation may be beneficial in light of evolving data and knowledge. Important considerations include the following:
    - Given the long half-life of CAB-LA and long-acting injectable LEN, exposure from dosing during pre-pregnancy/early pregnancy is likely to continue throughout the pregnancy; thus, the benefit of stopping CAB-LA or long-acting injectable LEN in pregnancy is uncertain.
    - If CAB-LA or long-acting injectable LEN is stopped during pregnancy and HIV exposure is ongoing, TDF/FTC as PrEP as well as additional strategies for HIV prevention should be encouraged.
- If pregnancy occurs while receiving PrEP, clinicians are encouraged strongly to register the pregnancy with the Antiretroviral Pregnancy Registry. The purpose of the Antiretroviral Pregnancy Registry is to detect any major teratogenic effect involving any of the registry drugs used during pregnancy, including ARV drugs used for PrEP.

Indications for PrEP as HIV prevention may change across periconception, antepartum, and postpartum periods. Therefore, discussions regarding the need for PrEP should be ongoing.

Laboratory Testing

Recommended laboratory testing when receiving PrEP during all stages of pregnancy (e.g., preconception, antepartum, postpartum, breastfeeding) includes—

- HIV diagnostic testing with an antigen/antibody combination immunoassay at baseline. With ongoing exposure to ARVs as PrEP, delays can be seen in antigen/antibody detection during acute infection.[35] Therefore, the CDC recommends antigen/antibody combination immunoassay as well as HIV-RNA testing every 3 months for oral TDF/FTC and prior to scheduled injections for CAB and LEN. HIV RNA testing is recommended prior to initial injections for CAB and LEN as feasible. PrEP administration should not be delayed while awaiting results. Testing can be offered more frequently if indicated based on clinical symptoms, while using PrEP regimens.
- HIV testing (i.e., antigen/antibody combination immunoassay, as well as HIV RNA testing) in the context of PrEP use during pregnancy should include HIV testing at entry into antenatal care, with re-testing in the second and third trimester. More frequent testing may be appropriate when clinically indicated (e.g., known adherence challenges) (see Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure).

- In the case of documented new HIV acquisition, discontinuation of PrEP and immediate referral to an HIV specialist for initiation of antiretroviral therapy are recommended (see Recommendations for Use of Antiretroviral Drugs During Pregnancy). During pregnancy and breastfeeding, appropriate care to prevent perinatal transmission should also be provided. See Early (Acute and Recent) HIV Infection and Previous Experience With Antiretroviral Medications but Not Currently on Antiretroviral Therapy During Current Pregnancy.
- For patients taking oral TDF/FTC as PrEP, renal function testing at baseline and every 12 months thereafter if <50 years of age and/or if estimated creatinine clearance (CrCl) over 90 mL/min. Otherwise, renal function should be monitored every 6 months. TDF/FTC as PrEP should not be initiated when there is a confirmed calculated CrCl <60 mL/min. Clinicians should discontinue daily TDF/FTC as PrEP if a person develops a confirmed calculated CrCl <50 mL/min.
- For patients considering PrEP with oral TDF/FTC (which has activity against hepatitis B), testing for hepatitis B virus (HBV) infection (i.e., hepatitis B surface antigen, hepatitis B core antibody, hepatitis B surface antibody) is indicated, but PrEP initiation need not be delayed while awaiting results. If there is no prior HBV infection and a lack of HBV immunity, HBV vaccination should be provided if HBV vaccination has not occurred or reimmunization should be considered if vaccination was previously provided but immunity is still lacking. In the context of chronic HBV, counseling should be provided regarding the risk of possible hepatitis flares when tenofovir-based PrEP is stopped.[36] See Hepatitis B Virus/HIV Coinfection.
- Pregnancy testing at baseline and then as indicated.
- Testing for STIs (e.g., gonorrhea, chlamydia, syphilis) at baseline. Testing every 6 months is recommended for gonorrhea and syphilis for women. Annual testing for chlamydia is also recommended. More frequent testing can be offered as clinically indicated.
- Reference to additional information and details about recommended laboratory testing in the CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline and Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis—United States, 2025 as needed.

Adherence Support

Daily Oral PrEP

Among 6,296 women participants from 11 post-approval studies of TDF/FTC PrEP, a pooled analysis [37] found no incident HIV diagnoses among women with consistent daily adherence to oral TDF/FTC. For women taking PrEP four to six times per week, the HIV incidence rate per 100 person-years was 0.13. Based on these findings among nonpregnant women, the Panel continues to recommend daily adherence but acknowledges that four to six doses per week achieves a high level of protection.

Before initiating PrEP, health care professionals should assess barriers to PrEP adherence and address concerns regarding PrEP use during the periconception, antepartum, and postpartum periods. Opportunities to promote adherence and mitigate barriers to adherence should be addressed at each visit. Data suggest that some adherence challenges stem from adherence fatigue, low perceptions of personal risk, stigma, cost, misinformation about PrEP, peer perspectives, mental health challenges, and intimate partner violence.[38-40] Based on barriers, health care professionals can discuss strategies tailored to individual needs to promote adherence and maximize benefits. Approaches include providing accurate information about the risks and benefits of PrEP, developing reminder strategies, and identifying supportive individuals as part of the health care team or the patient's social network who can provide social support toward PrEP adherence.

PrEP services are ideally delivered in a comprehensive manner and address social determinants of health—including how clients will access PrEP and related services—and address housing instability, access to health insurance, and transportation because these factors have been shown to interfere with adherence. The CDC provides PrEP webpages and a Compendium of Best Practices for PrEP provision.

Injectable PrEP

The implementation of injectable PrEP is new, and challenges with follow-up injections and care are anticipated. Patients and programs initiating injectable PrEP should develop systems and plans for facilitating follow-up care and plans for back-up methods of HIV prevention in the case of anticipated or unanticipated missed doses.[41,42]

Efficacy and Safety of Tenofovir Disoproxil Fumarate/Emtricitabine as PrEP During Pregnancy and Breastfeeding

Data from randomized controlled trials that enrolled men and women in heterosexual relationships demonstrated the efficacy of TDF/FTC PrEP to be 63% to 75%. In women with detectable drug levels (or taking PrEP), PrEP protected against 90% of incident transmissions.[37,43] Newer observational data from implementation studies suggest a dose-response curve with zero HIV incidence when taking seven doses per week, and lower but still high levels of protection when taking four to six doses per week.[37] Although participants planning for pregnancy were not enrolled in these clinical trials, subsequent data suggest that PrEP uptake and adherence are high during periconception periods.[13,44-46]

Currently available data suggest that the benefits of TDF/FTC as PrEP to prevent HIV during periconception, pregnancy, and breastfeeding periods outweigh any potential toxicities. PrEP is recommended by the CDC as an important HIV prevention strategy during periconception, pregnancy, and postpartum periods.[42,47,48] Additional data and primary sources describing what is known about TDF and FTC on birth outcomes, renal and bone effects for women, and renal and bone effects for infants exposed to TDF/FTC *in utero* or while breastfeeding are available in the Tenofovir Disoproxil Fumarate and Emtricitabine sections of these guidelines.[49,50]

Efficacy and Safety of Long-Acting Injectable Cabotegravir as PrEP During Pregnancy and Breastfeeding

CAB-LA is FDA approved[51] for use as PrEP in adults and adolescents, including during pregnancy or breastfeeding. HIV Prevention Trials Network (HPTN) 084 study compared CAB-LA to TDF/FTC among people with vaginal exposure to HIV and found HIV infection risk was 88% lower in the CAB-LA group, demonstrating superiority over oral TDF/FTC in preventing HIV.[52-54] Additional data and primary sources describing what is known about CAB-LA pharmacokinetics (PK) can be found in the CAB section (see Cabotegravir).

Safety and PK of CAB-LA injections continued during pregnancy [55-58] include data from the HPTN 084 Protocol Open Label Extension (OLE), in which, upon diagnosis of pregnancy, HIV-negative pregnant women were given the choice of continuing their current regimen (CAB-LA or TDF/FTC) or switching to the regimen of their choosing (CAB-LA or TDF/FTC) for HIV PrEP. In the

OLE, a total of 495 pregnancies were confirmed across all groups, of which 398 had CAB exposure at conception. Pregnancy-related maternal adverse event and adverse pregnancy outcome rates were similar across groups and similar to background rates.[54,59] Additional details can be found in the CAB section (see Cabotegravir).

CDC guidance notes that CAB-LA for PrEP may be initiated or continued if pregnancy occurs while receiving injections when anticipated benefits outweighing the risks.

Efficacy and Safety of Lenacapavir as PrEP During Pregnancy and Breastfeeding

In the PURPOSE 1 study, among 2,140 participants receiving LEN, 193 pregnancies occurred in 184 individuals exposed to LEN at conception. Pregnancy outcomes were similar to outcomes expected for the general population as well as outcomes seen in the oral PrEP control groups. Of the 186 pregnancies with LEN exposure with known outcomes, there were 128 live births and 60 losses, including elective terminations, spontaneous abortions, and stillbirths.[60] Serious events were uncommon, with gestational hypertension and hyperemesis gravidarum being the most frequently reported, and none were deemed related to LEN administration. A single minor congenital anomaly—polydactyly—was reported in an infant whose mother received LEN; the condition was consistent with a family history. PK data showed no significant differences in LEN exposure by pregnancy status or trimester, and while the drug was present in breast milk, infant exposure was minimal.[60] No HIV infections occurred among pregnant or breastfeeding participants receiving LEN. Additional data can be found in the LEN section (See Lenacapavir).

What Is Known About Other PrEP Agents During Periconception, Antepartum, and Postpartum Periods?

TAF/FTC for vaginal exposure to HIV is not approved by the FDA for HIV prevention, and the Panel does not recommend TAF/FTC as PrEP for this population, including during pregnancy and postpartum.[61] In the PURPOSE 1 study, adherence was low among participants on oral TAF/FTC, and the associated HIV incidence rate was not significantly different from the background HIV incidence.[61-63] Data regarding efficacy in women are still being explored, and some groups recommend TAF/FTC use for vaginal exposure to HIV when oral PrEP is desired and TAF/FTC is preferred or when TDF/FTC is otherwise contraindicated.[64]

The dapivirine vaginal ring also reduces the risk of HIV acquisition via receptive vaginal exposure and appears to be safe during pregnancy and breastfeeding. For the U.S. context, this product has been permanently withdrawn from the FDA approval process.[65-67]

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