# Tenofovir Alafenamide (Vemlidy, TAF)

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

Tenofovir alafenamide (TAF) is an orally bioavailable prodrug form of tenofovir (TFV). For information about tenofovir disoproxil fumarate (TDF), see the TDF section.

## Summary

- No dose adjustments are required for TAF during pregnancy.
- First-trimester exposure to TAF is not associated with increased risk of congenital anomalies.
- Emtricitabine (FTC)/TAF is not U.S. Food and Drug Administration approved for HIV pre-exposure prophylaxis (PrEP) in women.

## Human Studies in Pregnancy

### Pharmacokinetics

#### HIV Treatment

TAF pharmacokinetics (PK) can differ during pregnancy, depending on the concomitant antiretroviral (ARV) drugs administered. However, TAF exposures appear to be adequate in the second and third trimesters based on comparisons with historical data in nonpregnant adults.

TAF PK were evaluated as part of International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network P1026s in 31 women taking TAF 10 mg with cobicistat, 27 women taking TAF 25 mg without a pharmacoenhancer,[1] and 29 women taking TAF 25 mg with a pharmacoenhancer (cobicistat or ritonavir).[2] TAF area under the curve (AUC) did not differ between pregnancy and postpartum for women taking TAF 10 mg with cobicistat[1] or those taking TAF 25 mg with a pharmacoenhancer.[2] TAF AUC at a 25 mg dose without a pharmacoenhancer was 33% to 43% lower during pregnancy compared to postpartum but comparable to exposures in nonpregnant adults.[1] The Pharmacokinetics of newly developed ANtiretroviral agents in pregNAant women with HIV (PANNA) Network also evaluated TAF and TFV PK in 20 pregnant and postpartum European women receiving TAF 10 mg with cobicistat or TAF 25 mg without a pharmacoenhancer.[3] PK results from both dosing combinations were pooled and showed that TAF and TFV AUCs were 46% and 33% lower during pregnancy, respectively, than postpartum. Despite these decreases, 94% of pregnant women remained above the predefined TAF AUC efficacy target of 53.1 ng•h/mL. A separate study in pregnant women receiving TAF 25 mg with bictegravir and FTC showed that the total TAF AUC was approximately 22% to 43% lower during pregnancy than postpartum, but the unbound AUC was approximately 6% to 17% lower.[4] Trough concentrations of the active tenofovir-diphosphate form in peripheral blood mononuclear cells were comparable but variable between pregnancy and postpartum.

#### HIV Pre-exposure Prophylaxis

A study[5] of pregnant women without HIV randomized 1:1 to either TDF/FTC or TAF/FTC for PrEP reported TFV-DP in DBS was 44% higher at 8 weeks postpartum in comparison to the 8-week follow-up time point during pregnancy. TFV-DP in PBMC from participants receiving TAF/FTC were similar between pregnancy and postpartum[5] and were approximately eightfold higher than those

measured with TDF/FTC across all study visits, and were comparable to those measured in nonpregnant adults without HIV with 100% adherence[6] based on directly observed therapy.

## Placental and Breast Milk Passage

Limited data exist on TAF and TFV concentrations in placental blood and breast milk. TAF was below the assay limit of quantification (<3.9 ng/mL) in 43 of 44 cord blood samples tested and all infant washout samples in women receiving TAF 25 mg without a pharmacoenhancer[1] and in all cord blood and infant washout samples in women receiving TAF 25 mg with ritonavir or cobicistat. Maternal plasma TAF concentrations at delivery were measurable in only 4 of 45 paired samples in women receiving TAF 25 mg without a pharmacoenhancer[1] and in 2 of 25 paired samples in women receiving TAF 25 mg with ritonavir or cobicistat.[2] A separate study also did not detect TAF in any paired cord blood or maternal delivery samples, but it was able to quantify TFV and estimated a median placental transfer ratio of 0.81 from 13 paired samples.[3]

TAF breast milk transfer has been examined in smaller PK studies. One study examined TAF breast milk transfer in five breastfeeding women with HIV and identified a breast milk–to-plasma ratio of 4.09 for TAF[7] and a median estimated infant daily dose of 0.007 mg/kg. A separate PK study in eight breastfeeding women with hepatitis B virus (HBV) infection receiving TAF for at least 4 weeks estimated breast milk–to-plasma ratios for TAF and TFV to be 0.029 and 2.809, respectively.[8] The relative TAF dose was estimated at 0.005% of the maternal dose. TFV was detectable in the urine of three of seven infants at a median steady-state concentration of 5 ng/mL, which was 300 times less than urine concentrations measured in adults on TAF. TFV breast milk transfer was examined in 12 women receiving TAF 25 mg and 4 women receiving TDF 300 mg for HBV treatment.[9] TFV exposures in breast milk through 8 hours postdose were approximately fivefold higher at Day 3 postdelivery in women taking TAF than in women taking TDF. TFV concentrations with TAF decreased by 43% and 47% at 15 and 30 days postpartum, respectively, compared with Day 3. TFV has poor oral bioavailability, and TAF and infant plasma concentrations were not quantified, so the clinical relevance of higher TFV in breast milk with TAF is unclear.

## Teratogenicity

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for TAF and other ARV drugs twice a year through an interim report released in June and December. The APR has monitored sufficient numbers of first-trimester TAF exposures to detect at least a 1.5-fold increase in the risk of overall birth defects and at least a twofold increase in the risk of cardiovascular and genitourinary defects (the more common classes of birth defects in the general population). In the APR interim report, Figure 1. Summary of Birth Defects Among First Trimester Exposures provides a summary of the number and prevalence of birth defects per live births among cases of first-trimester exposure to TAF and other ARV drugs reported to the APR where there are sufficient data to determine 95% confidence intervals (CIs). The data in Figure 1 can be compared with the prevalence of birth defects in the U.S. population (2.72 birth defects per 100 live births) based on the Centers for Disease Control and Prevention birth defects surveillance system (Metropolitan Atlanta Congenital Defects Program [MACDP]) and with the Texas Birth Defects Registry (TBDR; 5.07 birth defects per 100 live births). Per the most recent APR interim report, the prevalence of birth defects is 4.07% (95% CI, 3.18–5.12) for TAF. This is statistically significantly elevated compared with MACDP (2.72%; 95% CI, 2.68–2.76) but not significantly different from TBDR (5.07%; 95% CI, 5.06–5.09). A detailed review of cases did not identify a pattern of birth defects for TAF. The prevalence and CIs will be refined with the continued accrual of additional exposed pregnancies.

### Adverse Pregnancy Outcomes

IMPAACT 2010/Virologic Efficacy and Safety of ART Combinations with TAF/TDF, EFV, and DTG (VESTED) was a randomized trial of dolutegravir (DTG)- and efavirenz (EFV)-containing antiretroviral therapy (ART) regimens in pregnancy, which found lower composite adverse outcomes in the group receiving DTG and FTC with TAF (DTG+FTC/TAF) than in the group receiving DTG and FTC with TDF (DTG+FTC/TDF) or EFV and FTC with TDF (EFV+FTC/TDF), and lower neonatal mortality than the arm receiving EFV+FTC/TDF (3.7% vs. 1.9%).[10] A *post hoc* risk–benefit analysis of weighted infant outcomes showed a more favorable overall tradeoff for infants born to mothers in the DTG+TAF/FTC arm than in the DTG+TDF/FTC and EFV+TDF/FTC arms.[11,12]

## Other Safety Data

### Maternal Safety Outcomes

The DTG+FTC/TAF arm of IMPAACT 2010/VESTED had higher maternal weight gain than the other two arms.[10] Although greater weight gain was seen in mothers receiving DTG+FTC/TAF, the extent of average weekly weight gain that occurred was still below the recommended amount by the Institute of Medicine. Follow-up analyses did not identify significant differences in metabolic issues between study arms as measured by hemoglobin A1C or random glucose levels among pregnant women or infants,[13] and they also showed that lower antepartum weight gain was associated with a higher risk of adverse pregnancy outcomes.[14] A separate analysis of metabolic markers in IMPAACT 2010/VESTED has also shown that mean total cholesterol, low-density lipoprotein cholesterol, triglycerides, and lipoprotein(a) were higher in women randomized to DTG+TAF/FTC in comparison to DTG+TDF/FTC, and high-density lipoprotein cholesterol was lower.[15] However, all lipids were still within normal reference ranges. The potential implications of excessive weight gain and other adverse safety outcomes when TAF-containing regimens are prescribed during pregnancy have also been evaluated in U.S.-based cohorts with variable findings.[16-18] A systematic analysis[14,19] of these collective studies identified a higher risk of excessive maternal weight gain and hypertensive disorders among pregnant women on TAF/integrase strand transfer inhibitor (INSTI) ART regimens in comparison to those not on a TAF/INSTI ART regimen but did not identify any differences in the risk of gestational diabetes mellitus. However, because TAF was administered with an INSTI across these studies, the effect of TAF alone could not be examined.

Renal safety has also been examined in a separate retrospective cohort of 100 pregnant women with HIV receiving TAF- or TDF-containing ART, and no significant differences in renal function, toxicity, or treatment discontinuations due to renal toxicity among regimens were identified.[18]

### Infant Safety Outcomes

Length-for-age z-scores and weight-for-age z-scores among infants exposed to DTG+TAF/FTC *in utero* did not significantly differ from those exposed to DTG+TDF/FTC at 26 or 50 weeks of age but were higher than those measured in infants exposed to EFV+TDF/FTC.[20] There were no differences in weight-for-length z-scores between treatment regimens. All infants showed severely stunted growth through the first year of age.

## Animal Studies

### Carcinogenicity

Carcinogenicity studies for TFV have only been performed with TDF, but given the lower TFV exposure with TAF, the associated carcinogenicity is assumed to be commensurate or lower. Refer to the Tenofovir Disoproxil Fumarate section for more information.

### Reproduction/Fertility

There is no evidence of impaired fertility or mating performance with TAF administration in rats or rabbits at exposures up to 53 times those seen in humans.[21]

### Teratogenicity/Adverse Pregnancy Outcomes

No effects on early embryonic development were seen in rats at TAF doses that produced exposures that were 62 times those seen in humans who received the therapeutic dose.[21]

### Placental and Breast Milk Passage

Rat studies demonstrated secretion of TFV in breast milk after administration of TDF, but secretion of TAF or TFV in animal milk after administration of TAF has not been evaluated.[21]

## Excerpt From Table 14

**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** |
|---|---|---|---|
| **Tenofovir Alafenamide** (TAF) *Vemlidy*<br><br>(TAF/BIC/FTC) *Biktarvy*<br><br>(TAF/FTC) *Descovy*<br><br>(TAF/EVG/c/FTC) *Genvoya*<br><br>(TAF/FTC/RPV) *Odefsey*<br><br>(TAF/DRV/c/FTC) *Symtuza* | **TAF (Vemlidy)**<br>• 25-mg tablet<br><br>**TAF/BIC/FTC (Biktarvy)**<br>• TAF 25-mg/ BIC 50-mg/FTC 200-mg tablet<br><br>**TAF/FTC (Descovy)**<br>• TAF 25-mg/FTC 200-mg tablet<br><br>**TAF/EVG/c/FTC (Genvoya)**<br>• TAF 10-mg/ EVG 150-mg/ COBI 150-mg/ FTC 200-mg tablet<br><br>**TAF/FTC/RPV (Odefsey)**<br>• TAF 25-mg/ FTC 200-mg/ RPV 25-mg tablet<br><br>**TAF/DRV/c/FTC (Symtuza)**<br>• TAF 10-mg/ DRV 800-mg/ COBI 150-mg/ FTC 200-mg tablet | **Pregnancy**<br><br>*PK in Pregnancy*<br>• AUC is lower in pregnancy, depending on the dose and concomitant ARV, but overall exposures are adequate.<br><br>*Dosing in Pregnancy*<br>• No change in dose indicated.<br><br>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).<br><br>**Standard Adult Doses**<br><br>*TAF (Vemlidy)*<br>• One tablet once daily with food<br><br>*TAF/BIC/FTC (Biktarvy)*<br>• One tablet once daily with or without food<br><br>*TAF/FTC (Descovy)*<br>• One tablet once daily with or without food<br>• Same dose (TAF 25 mg) can be used with or without PK enhancers.<br><br>*TAF/EVG/c/FTC (Genvoya)*<br>• One tablet once daily with food<br><br>*TAF/FTC/RPV (Odefsey)*<br>• One tablet once daily with food<br><br>*TAF/DRV/c/FTC (Symtuza)*<br>• One tablet once daily with food | **TAF**<br>• Low placental transfer to fetus[b]<br><br>**TFV**<br>• High placental transfer to fetus; plasma and cord blood concentrations lower than TDF[b]<br><br>No evidence of human teratogenicity (can rule out twofold increase in overall birth defects)<br><br>Renal function should be monitored because of the potential for renal toxicity.<br><br>**Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with TAF is contraindicated. |

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

## Excerpt From Table 14

[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

**Key:** ARV = antiretroviral; AUC = area under the curve; BIC = bictegravir; COBI = cobicistat; DRV/c = darunavir/cobicistat; EVG = elvitegravir; FDA = U.S. Food and Drug Administration; FTC = emtricitabine; PK = pharmacokinetic; RPV = rilpivirine; TAF = tenofovir alafenamide; TFV = tenofovir

## References


1. Brooks KM, Momper JD, Pinilla M, et al. Pharmacokinetics of tenofovir alafenamide with and without cobicistat in pregnant and postpartum women living with HIV. *AIDS*. 2021;35(3):407-417. Available at: https://pubmed.ncbi.nlm.nih.gov/33252495.

2. Brooks KM, Pinilla M, Stek AM, et al. Pharmacokinetics of tenofovir alafenamide with boosted protease inhibitors in pregnant and postpartum women living with HIV: results from IMPAACT P1026s. *J Acquir Immune Defic Syndr*. 2022;90(3):343-350. Available at: https://pubmed.ncbi.nlm.nih.gov/35195573.

3. Bukkems VE, Necsoi C, Hidalgo Tenorio C, et al. Tenofovir alafenamide plasma concentrations are reduced in pregnant women living with human immunodeficiency virus (HIV): data from the PANNA network. *Clin Infect Dis*. 2022;75(4):623-629. Available at: https://pubmed.ncbi.nlm.nih.gov/34864950/.

4. Zhang H, Hindman JT, Lin L, et al. A study of the pharmacokinetics, safety, and efficacy of bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed pregnant women with HIV. *AIDS*. 2023. Available at: https://pubmed.ncbi.nlm.nih.gov/37939141.

5. Joseph Davey D, Dadan S, Bheemraj K, et al. Evaluation of pharmacokinetics of tenofovir alafenamide (TAF) and tenofovir disoproxil (TDF) in pregnant and postpartum women in South Africa: PrEP-PP PK study. *Antiviral Res*. 2024;231:106014. Available at: https://pubmed.ncbi.nlm.nih.gov/39332538.

6. Yager JL, Brooks KM, Castillo-Mancilla JR, et al. Tenofovir-diphosphate in peripheral blood mononuclear cells during low, medium and high adherence to emtricitabine/ tenofovir alafenamide vs. emtricitabine/ tenofovir disoproxil fumarate. *AIDS*. 2021;35(15):2481-2487. Available at: https://pubmed.ncbi.nlm.nih.gov/34482350.

7. Aebi-Popp K, Kahlert CR, Crisinel PA, et al. Transfer of antiretroviral drugs into breastmilk: a prospective study from the Swiss Mother and Child HIV Cohort Study. *J Antimicrob Chemother*. 2022;77(12):3436-3442. Available at: https://pubmed.ncbi.nlm.nih.gov/36177836.

8. Kayes T, Crane H, Symonds A, et al. Plasma and breast milk pharmacokinetics of tenofovir alafenamide in mothers with chronic hepatitis B infection. *Aliment Pharmacol Ther*. 2022;56(3):510-518. Available at: https://pubmed.ncbi.nlm.nih.gov/35599363

9. Yang N, Zhou G, Cheng X, et al. Distribution evaluation of tenofovir in the breast milk of mothers with HBeAg-positive chronic HBV infection after treatment with tenofovir alafenamide and tenofovir disoproxil fumarate by a sensitive UPLC-MS/MS method. *Front Pharmacol*. 2021;12:734760. Available at: https://pubmed.ncbi.nlm.nih.gov/34483946/.

10. Lockman S, Brummel SS, Ziemba L, et al. Efficacy and safety of dolutegravir with emtricitabine and tenofovir alafenamide fumarate or tenofovir disoproxil fumarate, and efavirenz, emtricitabine, and tenofovir disoproxil fumarate HIV antiretroviral therapy regimens started in pregnancy (IMPAACT 2010/VESTED): a multicentre, open-label, randomised, controlled, phase 3 trial. *Lancet*. 2021;397(10281):1276-1292. Available at: https://pubmed.ncbi.nlm.nih.gov/33812487.

11. Brummel S, Ziemba L, Coletti A, et al. Risk-benefit trade-off for pregnancy and infant outcomes: DTG, EFV, TAF, and TDF. Type Presented at The Conference on Retroviruses and Opportunistic Infections; 2022, Year; Virtual Conference. Available at: https://www.impaactnetwork.org/sites/default/files/inline-files/IMPAACT2010_Brummel_DOOR_CROI2022_poster_0.pdf.

12. Fairlie L, Brummel S, Ziemba L, et al. Subsequent pregnancies in the IMPAACT 2010/VESTED Trial: high rate of adverse outcomes in women living with HIV. *J Acquir Immune Defic Syndr*. 2024;97(2):150-155. Available at: https://pubmed.ncbi.nlm.nih.gov/39742354.

13. Chinula L, Goldberg E, Ziemba L, et al. Pregnancy hemoglobin A1c and glucose with DTG vs EFV, TDF vs TAF: IMPAACT 2010. Type Presented at Conference on Retroviruses and Opportunistic Infections 12-16 February,2022, Year; Virtual Conference. Available at: https://www.impaactnetwork.org/sites/default/files/inline-files/IMPAACT2010_Chinula_HBA1C_Gluc_CROI2022_Poster_0.pdf.

14. Hoffman RM, Brummel S, Ziemba L, et al. Weight changes and adverse pregnancy outcomes with dolutegravir- and tenofovir alafenamide fumarate-containing antiretroviral treatment regimens during pregnancy and postpartum. *Clin Infect Dis*. 2024;78(6):1617-1628. Available at: https://pubmed.ncbi.nlm.nih.gov/38180851.

15. Eke AC, Brummel SS, Aliyu MH, et al. Lipid and Glucose Profiles in Pregnant Women With HIV on Tenofovir-based Antiretroviral Therapy. *Clin Infect Dis*. 2025;80(3):594-601. Available at: https://pubmed.ncbi.nlm.nih.gov/39219495.

16. Joseph NT, Satten GA, Williams RE, et al. The effect of antiretroviral therapy for the treatment of human immunodeficiency virus (HIV)-1 in pregnancy on gestational weight gain. *Clin Infect Dis*. 2022;75(4):665-672. Available at: https://pubmed.ncbi.nlm.nih.gov/34864949.

17. Nissim OA, Haney A, Lazenby GB. Effect of tenofovir alafenamide in combination with and without integrase inhibitors on weight gain, diabetes, and hypertensive disorders of pregnancy. *Pregnancy Hypertens*. 2023;34:47-52. Available at: https://pubmed.ncbi.nlm.nih.gov/37804587.

18. Thimm MA, Eke AC. Tenofovir, pregnancy and renal function changes in pregnant women living with HIV. *AIDS*. 2021;35(8):1319-1320. Available at: https://pubmed.ncbi.nlm.nih.gov/33710027.

19. Eke AC, Ramaiyer M, Eleje GU, et al. A systematic review and meta-analysis of maternal weight changes and pregnancy outcomes associated with integrase inhibitors and tenofovir alafenamide in pregnant women with HIV. *Am J Obstet Gynecol MFM*. 2024;6(8):101406. Available at: https://pubmed.ncbi.nlm.nih.gov/38866134.

20. Mbengeranwa TG, Ziemba L, Brummel SS, et al. Bone Mineral Content, Growth, and Renal Health of Infants With Perinatal Exposure to Maternal Dolutegravir Versus Efavirenz and Tenofovir Disoproxil Fumarate Versus Tenofovir Alafenamide: The Randomized IMPAACT 2010 (VESTED) Trial. *J Acquir Immune Defic Syndr*. 2025;99(2):211-219. Available at: https://pubmed.ncbi.nlm.nih.gov/40001275.

21. Descovy (emtricitabine and tenofovir alafenamide) [package insert]. Food and Drug Administration. 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208215s020lbl.pdf.