

Discovery for PrEP[®] (FTC/TAF) Renal Function Monitoring

This document is in response to your inquiry regarding renal function monitoring in individuals using Descovy for PrEP[®] (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis).

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf.

Product Labeling¹

Indication

FTC/TAF is indicated in at-risk adults and adolescents weighing ≥ 35 kg for PrEP to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating FTC/TAF for HIV-1 PrEP.

The indication does not include the use of FTC/TAF in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Warnings and Precautions

New onset or worsening renal impairment

Post-marketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy, and Fanconi syndrome have been reported with TAF-containing products; while most of these cases were characterized by potential confounders that may have contributed to the reported renal events, it is also possible these factors may have predisposed patients to tenofovir-related adverse events. FTC/TAF is not recommended in individuals with estimated CrCl of 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis.

Individuals taking tenofovir prodrugs who have impaired renal function and those taking nephrotoxic agents including non-steroidal anti-inflammatory drugs are at increased risk of developing renal-related adverse reactions.

Prior to or when initiating FTC/TAF, and during use of FTC/TAF on a clinically appropriate schedule, assess SCr, estimated CrCl, urine glucose, and urine protein in all individuals. In individuals with chronic kidney disease, also assess serum phosphorus. Discontinue FTC/TAF in individuals who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.

Use in Specific Populations

Renal impairment

No dosage adjustment of FTC/TAF is recommended in individuals with estimated CrCl ≥ 30 mL/min, or in adults with end-stage renal disease (estimated CrCl < 15 mL/min) who are receiving chronic hemodialysis. On days of hemodialysis, administer the daily dose of FTC/TAF after completion of hemodialysis treatment.

Clinical Guidelines

Please refer to the clinical guidelines for recommendations that address the frequency of renal function assessment during the use of FTC/TAF for HIV-1 PrEP. The inclusion of these guidelines should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences, Inc. Providers should use their clinical judgment to determine the appropriate schedule for renal function assessment.

Centers for Disease Control and Prevention²

For patients taking FTC/TAF, assess kidney function by estimated CrCL before starting PrEP. Monitor estimated CrCl every 6 months for patients aged ≥ 50 years or for those who had an estimated CrCl < 90 mL/min when they initiated oral PrEP. Monitor estimated CrCl every 12 months for all patients continuing oral PrEP. More frequent monitoring may be appropriate for patients with additional risk factors for kidney disease.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Centers for Disease Control and Prevention (CDC). Clinical Guidance for PrEP. Available at: <https://www.cdc.gov/hivnexus/hcp/prep/index.html>. Last Updated: 30 April 2026.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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