Make plans with their future in mind

Have you considered RENAL FUNCTION when prescribing PrEP?

#1 The overall **prescribed PrEP medication** by infectious disease specialists

Source: IQVIA LAAD Weekly, 06/26/2020 through 08/16/2024.*

*This information is an estimate derived from the use of information under license from the following IQVIA® information service: IQVIA Longitudinal Access and Adjudication Data (LAAD) for the period week ending (WE) 05/31/2020 through WE 08/16/2024 and WE 10/09/2019 through WE 08/16/2024. IQVIA expressly reserves all rights, including rights of copying, distribution and republication.

INDICATION & LIMITATION OF USE

DESCOVY® for HIV-1 pre-exposure prophylaxis (PrEP) is indicated in at-risk adults and adolescents (≥35 kg) to reduce the risk of sexually acquired HIV-1 infection, excluding individuals at risk from receptive vaginal sex. HIV-1–negative status must be confirmed immediately prior to initiation.

Limitation of Use: DESCOVY FOR PrEP® is not indicated in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
for **PrEP** pre-exposure prophylaxis

Take Pride in their PrEP

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF DESCOVY FOR PrEP® IN UNDIAGNOSED EARLY HIV-1 INFECTION and POST-TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **DESCOVY FOR PrEP must be prescribed only to individuals confirmed to be HIV negative immediately prior to initiation and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with use of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate if signs or symptoms of acute HIV-1 infection are present unless HIV-negative status is confirmed**
- **Severe acute exacerbations of hepatitis B have been reported in individuals infected with hepatitis B virus (HBV) who discontinued products containing FTC and/or TDF and may occur with discontinuation of DESCOVY®. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in individuals with HBV who discontinue DESCOVY. If appropriate, anti-hepatitis B therapy may be warranted**

Warnings and precautions

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)-containing products. Do not initiate DESCOVY in individuals with estimated creatinine clearance (CrCl) <30 mL/min. Individuals with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue DESCOVY in individuals who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all individuals (see Dosage and Administration section)

Please see additional Important Safety Information throughout and full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING**.

Consider renal function over the long term when choosing a PrEP option

Renal function may change over time due to age and other factors[1-15]*

Age is a common consideration, as eGFR may decline over time[2]

Mean GFR values across life span in males

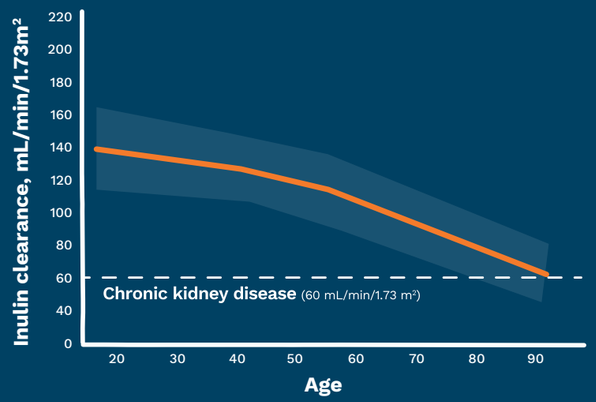

Chart reprinted with permission from Elsevier.

Renal risk factors may be more prevalent than you think[3]:

62% of oral PrEP users had ≥1 renal risk factor

(Retrospective US observational study, January 2015-February 2020; N=40,621)

BEHAVIORAL FACTORS

Anabolic steroid use

Anabolic steroids were shown to **cause or exacerbate chronic kidney disease** in a 2019 systematic review[4]
(Davani-Davari D, et al; 2019)

Excessive alcohol consumption

According to the National Kidney Foundation, **regular heavy drinking** may double the risk of **chronic kidney disease**[5]
(National Kidney Foundation, 2014)

Cocaine use

According to a 2021 study, in addition to causing acute kidney injury, **cocaine use has been associated with progressive chronic kidney disease**[6]
(Xiao N, et al; 2021; A lifetime use of cocaine reported in 2019 among adolescents and young adults)

Stimulant use

Stimulants, such as methamphetamines and cocaine, have been associated with a **negative effect on kidney health**[7]
(Fields SD and Tung E; 2021; Narrative review of patient-focused selection of PrEP medication for individuals at risk of HIV)

Smoking

Current and former smokers had **significantly increased odds of chronic kidney disease** compared with never smokers, according to a 2021 systematic review and meta-analysis of 104 studies from inception through June 2019[8]
(Kelly JT, et al; 2021)

CONCOMITANT MEDICATIONS

NSAIDs

Taking **≥7 doses of NSAIDs per month** can significantly **increase the risk of kidney disease**, according to a 2011-2014 cohort study of US Army soldiers[9]
(Nelson DA, et al; 2019; N=764,228)

Proton pump inhibitors

PPI use was shown to causally **increase the risk for incident CKD, CKD progression, and ESKD**, according to a 2020 review of 12 large-cohort studies[10]
(Al-Aly Z, et al; 2020; Sampling period between 1993-2012)

COMORBIDITIES

Chronic kidney disease or declining renal function

According to the CDC, **more than 1 in 7 US adults** were estimated to have CKD; as many as 9 in 10 adults with CKD did not know they had CKD[11]
(CDC; 2021)

Comorbidities in adolescents

Individuals with **prediabetes** are at **increased risk of chronic kidney disease in adulthood**[12]
(Andes LJ, et al; 2019; Cross-sectional analyses of the 2005-2016 NHANES; N=5786 individuals)

Diabetes

According to the CDC, **diabetes is the leading cause of kidney failure**; **~1 in 3** adults with diabetes may have **CKD**[11]
(CDC; 2021)

Obesity

Obesity is associated with a **~2X higher risk of developing chronic kidney disease**, according to a 2021 systematic review and meta-analysis of prospective or retrospective cohort studies[13]
(Pinto KRD, et al; 2021)

Hypertension

According to the CDC, **hypertension** is the **second leading cause of kidney failure**. Men are at greater risk for CKD and ESRD than women[11,14]
(CDC; 2021; Weldegiorgis M and Woodward M; 2020; N=2,382,712)

eGFR=estimated glomerular filtration rate.
*Not an exhaustive list of all known renal risk factors.

AAP=American Academy of Pediatrics; BP=blood pressure; CDC=Centers for Disease Control and Prevention; CKD=chronic kidney disease; eGFR=estimated glomerular filtration rate; ESKD=end-stage kidney disease; ESRD=end-stage renal disease; GRF=glomerular filtration rate; NHANES=National Health and Nutrition Examination Survey; NSAID=non-steroidal anti-inflammatory drug; PPI=proton pump inhibitor.

99.7% remained HIV negative with DESCOVY®[15]

DISCOVER is the largest PrEP clinical trial, with over 5300 participants[15-17]

Primary endpoint and 96-week analysis: Randomized, double-blind study of HIV-seronegative MSM and TGW* receiving once-daily **DESCOVY** (n=2694) or **FTC/TDF** (n=2693).

Powerful HIV prevention[15,16]

DESCOVY FOR PrEP was noninferior to FTC/TDF through 96 weeks.

At primary endpoint analysis†: **0.16/100 PY** vs **0.34/100 PY** (IRR=0.47; CI: 0.19-1.15).
At 96 weeks‡: **0.16/100 PY** vs **0.30/100 PY** (IRR=0.54; CI: 0.23-1.26).

99.7% **DESCOVY** (n=2670) vs **99.4%** **FTC/TDF** (n=2665)
of participants remained HIV negative at both time points.

*Study enrollment criteria: HIV-seronegative men and TGW who have sex with men who were at risk of HIV and reported condomless anal sex with ≥2 partners in the prior 12 weeks; or syphilis, rectal gonorrhea, or chlamydia in the prior 24 weeks.
†When 100% of participants reached Week 48 and ≥50% reached Week 96.
‡When 100% of participants reached Week 96.

CI=confidence interval; FTC/TDF=emtricitabine/tenofovir disoproxil fumarate; IRR=incidence rate ratio; MSM=men who have sex with men; PY=person-years; TGW=transgender women.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindication

- DESCOVY FOR PrEP is contraindicated in individuals with unknown or positive HIV status

Warnings and precautions

- **Comprehensive management to reduce risks:**
  - Use DESCOVY FOR PrEP to reduce the risk of HIV-1 infection as part of a comprehensive strategy that includes adherence to daily dosing and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs)
  - **HIV-1 risk factors:** Behavioral, biological, or epidemiologic HIV-1 risk factors may include, but are not limited to: condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high-prevalence area or network
  - **Reduce STI risk:** Counsel on the use of STI prevention measures (e.g., consistent and correct condom use, knowledge of partner's HIV-1 viremic status, regular testing for STIs)
  - **Reduce potential for drug resistance:** Only prescribe DESCOVY FOR PrEP to individuals confirmed to be HIV negative immediately prior to initiation, at least every 3 months while taking DESCOVY, and upon an STI diagnosis. HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only DESCOVY because DESCOVY alone is not a complete regimen for treating HIV-1

Demonstrated long-term safety profile at ≥96 weeks[15,16]

- Few participants discontinued due to adverse events, regardless of severity (**1%** vs 2%)
- Most common adverse reactions (all grades) reported in ≥2% of participants **were similar in both study arms** and included diarrhea, nausea, headache, fatigue, and abdominal pain or discomfort

Less long-term impact on eGFR at ≥96 weeks[15]

Median change from baseline in eGFR through Week 96*

	Week 48	Week 96
DESCOVY FOR PrEP	**+1.6 mL/min** (n=2369)	**+3.7 mL/min** (n=2193)
FTC/TDF	**-2.3 mL/min** (n=2366)	**-0.4 mL/min** (n=2217)

The long-term clinical significance of changes in eGFR is not known.

Lower serum creatinine levels were also seen with DESCOVY FOR PrEP through Week 96

- Median serum creatinine **decreased 0.02 mg/dL with DESCOVY FOR PrEP** vs a **0.01 mg/dL decrease with FTC/TDF** from baseline at Week 96
- **DESCOVY FOR PrEP** can be used in people with impaired renal function of CrCl ≥30 mL/min

*Baseline values: 123 mL/min for DESCOVY; 121 mL/min for FTC/TDF.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Comprehensive management to reduce risks:** (cont'd)
  - Some HIV tests may not detect acute HIV infection. Prior to initiating DESCOVY FOR PrEP, ask individuals about potential recent exposure events. If recent (<1 month) exposures are reported or suspected, or symptoms of acute HIV infection (e.g., fever, fatigue, myalgia, skin rash) are present, confirm HIV-negative status with a test approved by the FDA for use in the diagnosis of acute HIV infection
  - If HIV-1 infection is suspected or if symptoms of acute infection are present while taking DESCOVY FOR PrEP, convert the DESCOVY FOR PrEP regimen to a complete HIV treatment regimen until HIV-negative status is confirmed by a test approved by the FDA for use in the diagnosis of acute HIV infection
  - **Counsel on adherence:** Counsel individuals to strictly adhere to daily dosing, as efficacy is strongly correlated with adherence. Some individuals, such as adolescents, may benefit from more frequent visits and counseling

Please see additional Important Safety Information throughout and full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING**.

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
for PrEP pre-exposure prophylaxis

CrCl=creatinine clearance.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)-containing products. Do not initiate DESCOVY in individuals with estimated creatinine clearance (CrCl) <30 mL/min. Individuals with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue DESCOVY in individuals who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all individuals (see Dosage and Administration section)
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue use if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations

Adverse reactions

- **Most common adverse reactions** (≥2%) in the DESCOVY FOR PrEP clinical trial were diarrhea, nausea, headache, fatigue, and abdominal pain

Drug interactions

- **Prescribing information:** Consult the full Prescribing Information for DESCOVY for more information, warnings, and potentially significant drug interactions, including clinical comments
- **Metabolism:** Drugs that inhibit P-gp can increase the concentrations of TAF, a component of DESCOVY. Drugs that induce P-gp can decrease the concentrations of TAF, which may lead to loss of efficacy
- **Drugs affecting renal function:** Coadministration of DESCOVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions

Dosage and administration

- **Dosage:** One tablet (emtricitabine 200 mg/tenofovir alafenamide 25 mg) taken once daily with or without food
- **HIV screening:** Test for HIV-1 infection immediately prior to initiating, at least every 3 months during use, and upon diagnosis of an STI (see Warnings and Precautions section)
- **HBV screening:** Test for HBV infection prior to or when initiating DESCOVY
- **Renal impairment and monitoring:** Not recommended in individuals with CrCl <30 mL/min. Prior to or when initiating DESCOVY, and during use on a clinically appropriate schedule, assess serum creatinine, CrCl, urine glucose, and urine protein in all individuals. In individuals with chronic kidney disease, assess serum phosphorus

References:

1. Chan L, Asriel B, Eaton EF, Wyatt CM. Potential kidney toxicity from the antiviral drug tenofovir: new indications, new formulations, and a new prodrug. *Curr Opin Nephrol Hypertens*. 2018;27(2):102-112. doi:10.1097/MNH.0000000000000392 **2.** Stevens LA, Coresh J, Greene T, Levey AS. Assessing kidney function—measured and estimated glomerular filtration rate. *N Engl J Med*. 2006;354(23):2473-2483. doi:10.1056/NEJMra054415 **3.** Fields SD, Gruber J, Clue J, Rey GG, Cuervo HD. Prevalence of renal and bone risk factors among individuals prescribed oral pre-exposure prophylaxis for HIV. *IJID Reg*. 2023;6:68-75. doi:10.1016/j.ijregi.2023.01.004 **4.** Davani-Davari D, Karimzadeh I, Khalili H. The potential effects of anabolic-androgenic steroids and growth hormone as commonly used sport supplements on the kidney: a systematic review. *BMC Nephrol*. 2019;20(1):198. doi:10.1186/s12882-019-1384-0 **5.** National Kidney Foundation. Drinking alcohol affects your kidneys. Published August 12, 2014. Accessed June 10, 2024. https://www.kidney.org/news/kidneyCare/winter10/AlcoholAffects **6.** Xiao N, Chai H, Omoloja A. Substance use among adolescents and young adults with chronic kidney disease or kidney failure. *Pediatr Nephrol*. 2021;36(11):3585-3593. doi:10.1007/s00467-021-05001-2 **7.** Fields SD, Tung E. Patient-focused selection of PrEP medication for individuals at risk of HIV: a narrative review. *Infect Dis Ther*. 2021;10(1):165-186. doi:10.1007/s40121-020-00384-5 **8.** Kelly JT, Su G, Zhang L, et al. Modifiable lifestyle factors for primary prevention of CKD: a systematic review and meta-analysis. *J Am Soc Nephrol*. 2021;32(1):239-253. doi:10.1681/ASN.2020030384 **9.** Nelson DA, Marks ES, Deuster PA, O'Connor FG, Kurina LM. Association of nonsteroidal anti-inflammatory drug prescriptions with kidney disease among active young and middle-aged adults. *JAMA Netw Open*. 2019;2(2):e187896. doi:10.1001/jamanetworkopen.2018.7896 **10.** Al-Aly Z, Maddukuri G, Xie Y. Proton pump inhibitors and the kidney: implications of current evidence for clinical practice and when and how to deprescribe. *Am J Kidney Dis*. 2020;75(4):497-507. doi:10.1053/j.ajkd.2019.07.012 **11.** Centers for Disease Control and Prevention. Chronic kidney disease in the United States, 2021 [infographic]. Updated March 4, 2021. Accessed June 10, 2024. https://nccd.cdc.gov/CKD/Documents/Chronic-Kidney-Disease-in-the-US-2021-h.pdf **12.** Andes LJ, Cheng YJ, Rolka DB, Gregg EW, Imperatore G. Prevalence of prediabetes among adolescents and young adults in the United States, 2005-2016. *JAMA Pediatr*. 2020;174(2):e194498. doi:10.1001/jamapediatrics.2019.4498 **13.** Pinto KRD, Feckinghaus CM, Hirakata VN. Obesity as a predictive factor for chronic kidney disease in adults: systematic review and meta-analysis. *Braz J Med Biol Res*. 2021;54(4):e10022. doi:10.1590/1414-431X202010022 **14.** Weldegiorgis M, Woodward M. The impact of hypertension on chronic kidney disease and end-stage renal disease is greater in men than women: a systematic review and meta-analysis. *BMC Nephrol*. 2020;21(1):506. doi:10.1186/s12882-020-02151-7 **15.** Ogbuagu O, Ruane PJ, Podzamczer D, et al; the DISCOVER study team. Long-term safety and efficacy of emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV-1 pre-exposure prophylaxis: week 96 results from a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet HIV*. 2021;8(7):e397-e407. doi:10.1016/S2352-3018(21)00071-0 **16.** DESCOVY. Package insert. Gilead Sciences, Inc.; 2022. **17.** TRUVADA. Package insert. Gilead Sciences, Inc.; 2020.

Please see additional Important Safety Information throughout and full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING**.

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
for PrEP pre-exposure prophylaxis

Over 98% of Gilead Advancing Access® Co-pay Coupon Card users pay $0 each month for DESCOVY FOR PrEP®*†

- The Gilead Co-pay Coupon Card program may help eligible, commercially insured individuals lower their out-of-pocket costs*
- This program covers up to $7200 in co-pays per year with no monthly limit for DESCOVY FOR PrEP

Call 1-800-226-2056

Monday–Friday, 9 AM to 8 PM ET, for more information.

Learn more about the Advancing Access® program

*Co-pay coupon support is available for commercially insured, eligible individuals only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit gileadadvancingaccess.com/copay-coupon-card. This is not health insurance. Only accepted at participating pharmacies.

† Source: Data on file; as of 03/31/2024.

INDICATION & LIMITATION OF USE

DESCOVY® for HIV-1 pre-exposure prophylaxis (PrEP) is indicated in at-risk adults and adolescents (≥35 kg) to reduce the risk of sexually acquired HIV-1 infection, excluding individuals at risk from receptive vaginal sex. HIV-1–negative status must be confirmed immediately prior to initiation.

Limitation of Use: DESCOVY FOR PrEP® is not indicated in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Please see additional Important Safety Information throughout and full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING on risk of drug resistance with the use of DESCOVY FOR PrEP in undiagnosed early HIV-1 infection and post-treatment acute exacerbation of hepatitis B.**

K. Haring

Artwork © Keith Haring Foundation. Licensed by Artestar, New York.

Visit DESCOVYhcp.com

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets
for PrEP pre-exposure prophylaxis

Take Pride in their PrEP