Have you considered BONE MINERAL DENSITY 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**

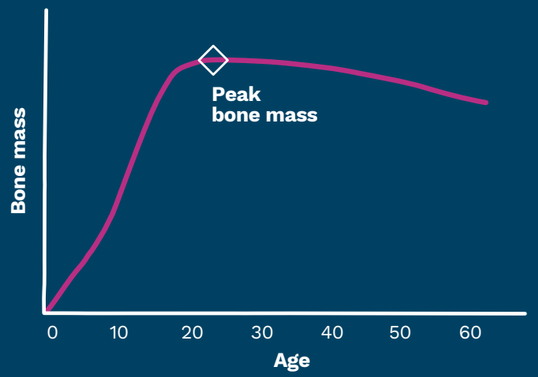
Please see additional Important Safety Information throughout and full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING**.

Consider BMD over the long term when choosing a PrEP option

BMD may be impacted by age and other risk factors[1-13]*

Bone density develops through **about age 30** and decreases as people age.[1]

Bone mass across life span in cisgender males



(Weaver, 2016; Adapted by permission from Springer Nature: Osteoporosis International. The Natural Osteoporosis Foundation's position statement on peak bone mass development and lifestyle factors: a systematic review and implementation recommendations)

Bone risk factors may be more prevalent than you think[2]:

68% of oral PrEP users had ≥1 bone risk factor

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

BEHAVIORAL FACTORS

Excessive alcohol consumption

Excessive alcohol intake could significantly **increase the risk of osteoporosis-related fractures**[3]

(Fields SD and Tung E; 2021. Narrative review of patient-focused selection of PrEP medication for individuals at risk for HIV)

Inhalant use

Low BMD was associated with the use of **inhalants (eg, poppers) in MSM** enrolled (n=210) at the San Francisco Department of Public Health site of the US CDC PrEP study from 2005-2007[4]

(Liu AY, et al; 2011)

Methamphetamine use

Low BMD was associated with the use of **methamphetamines in MSM** enrolled (n=210) at the San Francisco Department of Public Health site of the US CDC PrEP study from 2005-2007[4]

(Liu AY, et al; 2011)

Opioid use

Some commonly used opioids were shown to have a **negative effect on bone**[5]

Some of the negative effects of certain opioids include:
Morphine: osteoporosis, osteopenia, increased risk of fracture.
Methadone: osteoporosis, osteopenia, increased risk of fracture, decrease in bone mineral density.

(Márquez-Grant N, et al; 2022)

Smoking

Smoking was shown to **increase the risk of bone fracture and reduce bone mass,** according to a 2018 review of 27 studies[6]

(Al-Bashaireh AM, et al; 2018)

Vaping

46% higher prevalence of self-reported fragility fractures† among e-cigarette users‡ vs non-users, according to 2017-2018 NHANES data[7]

(Agoons DD, et al; 2021. Data on 5569 individuals aged >20 years; 1050 [18.8%] were past or present e-cigarette users)

†In hip, spine, or wrist.
‡Past or present users.

CONCOMITANT MEDICATIONS

ADHD medications

Stimulant ADHD medication usage was associated with a statistically significant **decrease in BMD** in the skull and spine,§ according to DXA data from the 2013-2018 NHANES of individuals aged 18 to 50 years[8]

ADHD medications reported in the NHANES include amphetamine, methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine, and lisdexamfetamine. (Lawson MJ, et al; 2022; N=7961 [ADHD medication users, n=79 and controls, n=7871])

§No differences in BMD were seen in any other skeletal region.

Antidepressants

In a 2022 systematic review and meta-analysis, **the use of SSRIs was associated with a decrease of BMD**[9]

(Mercurio M, et al; 2022. The use of antidepressants is linked to bone loss: a systematic review and meta-analysis)

Proton pump inhibitors

PPI use was associated with a **26% increased risk of hip fracture** as compared to non-PPI users, according to a 2018 systematic review and observational meta-analysis of 17 case-controlled and cohort studies from inception to January 2018[10]

(Hussain S, al; 2018)

COMORBIDITIES

Osteopenia/osteoporosis (Younger males)

>1 in 4 men (28%) had osteopenia at the femoral neck in a cross-sectional study of individuals aged 35 to 50 years (N=173; 81 were male)[11]

(Bass MA, et al; 2019)

Low BMD (TGW)

In a 2020 Italian cross-sectional study that evaluated fracture risk in 57 TGW on estrogen replacement therapy after gender-confirming surgery, **1 out of 7 showed an intermediate-high 10-year fracture risk**[12,13¶]

(Motta G, et al; 2020)

¶Participants (≥18 years old) were recruited from Turin, Italy, from January 2012 to May 2018.

BMD=bone mineral density.
*Not an exhaustive list of all known risk factors.

ADHD=attention-deficit/hyperactivity disorder; CDC=Centers for Disease Control and Prevention; DXA=dual-energy X-ray absorptiometry; LAAD=Longitudinal Access and Adjudication Data; MSM=men who have sex with men; NHANES=National Health and Nutrition Examination Survey; PPI=proton pump inhibitor; SSRI=selective serotonin reuptake inhibitor. SSRI is one class of drugs used to treat depression; TGW=transgender women.

99.7% remained HIV negative with DESCOVY®[14]

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

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[14,15]

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.

Demonstrated safety profile at ≥96 weeks[14,15]

- 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

Significantly less impact on BMD through ≥96 weeks[14,16,17]

- 24% to 29% of participants in the DISCOVER BMD substudy (n=383; median age, 37 years) had osteopenia or osteoporosis at baseline

Mean % change in BMD from baseline through 96 weeks*:	Lumbar spine		Hip	
	Week 48	Week 96	Week 48	Week 96
DESCOVY FOR PrEP	**+0.5%** (n=159)	**+1.0%** (n=144)	**+0.2%** (n=158)	**+0.6%** (n=140)
FTC/TDF	**-1.1%** (n=160)	**-1.4%** (n=140)	**-1.0%** (n=158)	**-1.0%** (n=137)

*p<0.0001

- **Consistent results seen in a subgroup of participants <25 years of age**

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

BMD declines by site (**DESCOVY** and **FTC/TDF**):

- **≥5% at lumbar spine:** 4% in both treatment arms at Week 48; **4%** and **16%** at Week 96
- **≥7% at total hip:** 1% in both arms at Week 48; **0%** and **1%** at Week 96
- Analysis of these parameters was conducted in a subset of the study population (n=383)

Median age for the substudy was 37 years, with participants ranging from 19 to 74 years of age.

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

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

FTC/TDF=emtricitabine/tenofovir disoproxil fumarate; PY=person-years.

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. Weaver CM, Gordon CM, Janz KF, et al. The National Osteoporosis Foundation's position statement on peak bone mass development and lifestyle factors: a systematic review and implementation recommendations. *Osteoporos Int*. 2016;27(4):1281-1386. doi:10.1007/s00198-015-3440-3 **2.** 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 **3.** 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 **4.** Liu AY, Vittinghoff E, Sellmeyer DE, et al. Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. *PLoS One*. 2011;6(8):e23688. doi:10.1371/journal.pone.0023688 **5.** Márquez-Grant N, Baldini E, Jeynes V, et al. How do drugs affect the skeleton? Implications for forensic anthropology. *Biology (Basel)*. 2022;11(4):524. doi:10.3390/biology11040524 **6.** Al-Bashaireh AM, Haddad LG, Weaver M, Chengguo X, Kelly DL, Yoon S. The effect of tobacco smoking on bone mass: an overview of pathophysiologic mechanisms. *J Osteoporos*. 2018:1206235. doi:10.1155/2018/1206235 **7.** Agoons DD, Agoons BB, Emmanuel KE, Matawalle FA, Cunningham JM. Association between electronic cigarette use and fragility fractures among US adults. *Am J Med Open*. 2021;1-6:100002. doi.org/10.1016/j.ajmo.2021.100002 **8.** Lawson MJ, Beltran TA, Padillla CR, Berry-Cabán CS, Choi YS. Attention deficit hyperactivity disorder medications and bone mineral density of adults in the United States. *Bone Rep*. 2022;16:101570. doi:10.1016/j.bonr.2022.101570 **9.** Mercurio M, de Filippis R, Spina G, et al. The use of antidepressants is linked to bone loss: a systematic review and metanalysis. *Orthop Rev (Pavia)*. 2022;14(6):38564. doi:10.52965/001c.38564 **10.** Hussain S, Siddiqui AN, Habib A, Hussain MS, Najmi AK. Proton pump inhibitors' use and risk of hip fracture: a systematic review and meta-analysis. *Rheumatol Int*. 2018;38(11):1999-2014. doi:10.1007/s00296-018-4142-x **11.** Bass MA, Sharma A, Nahar VK, et al. Bone mineral density among men and women aged 35 to 50 years. *J Am Osteopath Assoc*. 2019;119(6):357-363. doi:10.7556/jaoa.2019.064 **12.** Data on file. Gilead Sciences, Inc. **13.** Motta G, Marinelli L, Barale M, et al. Fracture risk assessment in an Italian group of transgender women after gender-confirming surgery. *J Bone Miner Metab*. 2020;38(6):885-893. doi:10.1007/s00774-020-01127-9 **14.** 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 **15.** DESCOVY. Package insert. Gilead Sciences, Inc.; 2022. **16.** 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 **17.** Wohl DA, Ruane PJ, Hosek S, et al. Bone safety outcomes with F/TAF vs F/TDF for PrEP in the DISCOVER trial. Presented at: IDWeek 2019; October 2-6, 2019; Washington, DC. Poster 1288.

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