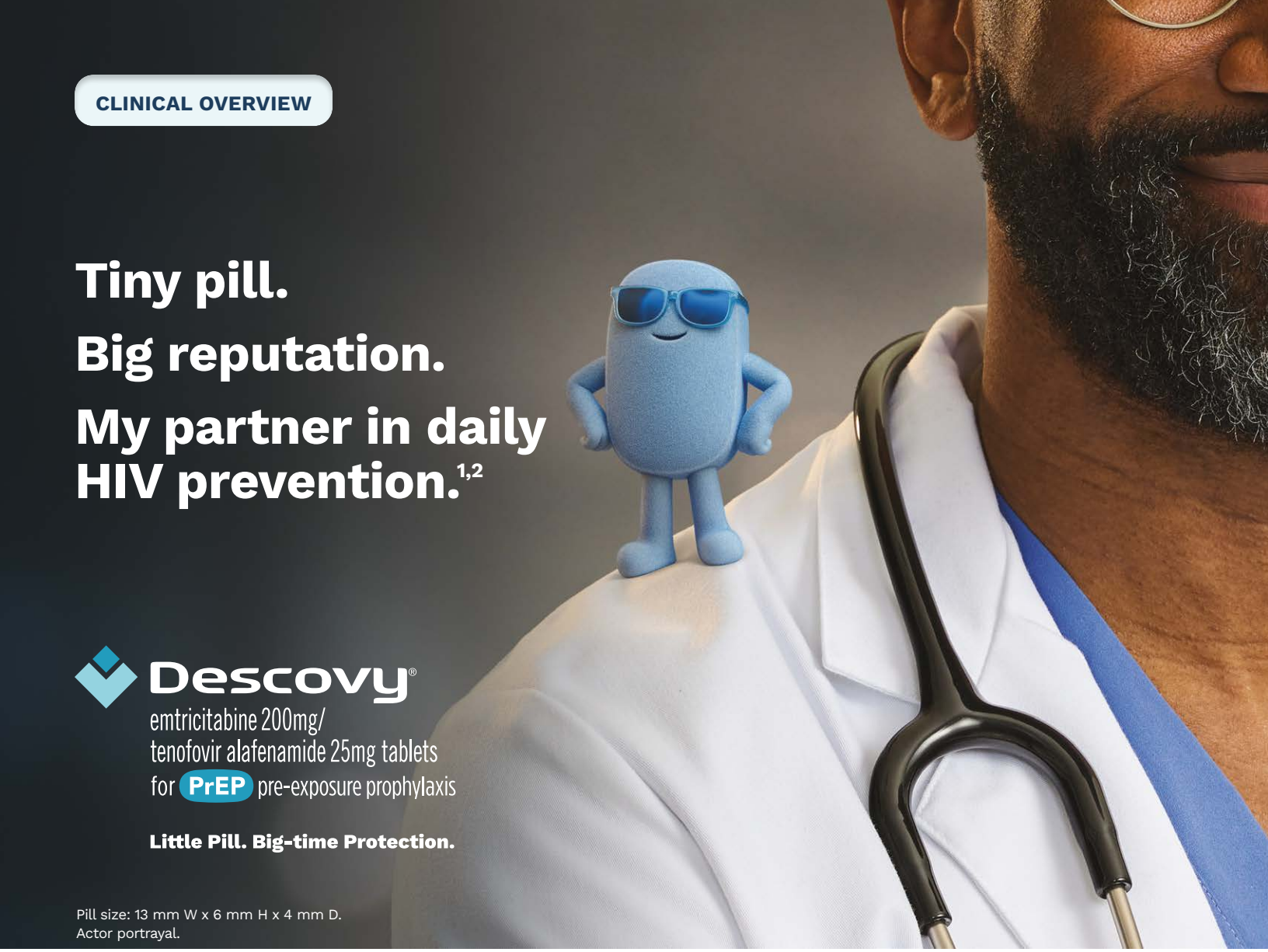
CLINICAL OVERVIEW

Tiny pill.
Big reputation.
My partner in daily HIV prevention.[1,2]



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

Little Pill. Big-time Protection.

Pill size: 13 mm W x 6 mm H x 4 mm D.
Actor portrayal.

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.

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**.

PrEP is highly effective for preventing HIV[3]

According to the CDC, PrEP can reduce the chance of contracting HIV through sex by ~99% when taken as prescribed[3]

After 40 years of progress in reducing new HIV diagnoses, HIV remains a public health focus[4]

Only 36% of the **1.2M people** indicated for PrEP in 2022 **were prescribed a PrEP medication[5]**

(CDC, 2022 US estimate for individuals aged ≥16 years)

Groups most impacted by HIV continue to have low rates of PrEP use[6]

In a retrospective analysis of PrEP prescriptions, Black and Latine people were disproportionately underprescribed PrEP relative to their need for HIV prevention[6]

PrEP users vs new HIV diagnoses by race and ethnicity[6]



Black and Latino communities represent a key opportunity to close gaps in HIV prevention.[6]

CDC=Centers for Disease Control and Prevention; PrEP=pre-exposure prophylaxis.

KEY POPULATIONS/PrEP DURATION/BONE AND RENAL RISK FACTORS

PrEP use can be long term[7,8]

A real-world study looked at ~14,000 people[a] who received PrEP care during a 6-year period[7]

(July 2012-March 2019; N=13,906)

Individuals engaged with PrEP care at any point during the retrospective study period[7]:

- **52.2%** of those initiating PrEP discontinued at least once during the study
- **60.2%** of those who discontinued reinitiated PrEP before the end of follow-up

(Hojilla JC, et al; 2021. Study used electronic health records from Integrated Health System in Northern California)
[a] Prescriptions were filled for FTC/TDF or FTC/TAF for individuals aged ≥18 years with an indication for PrEP.[7]

PrEP was first approved by the FDA in 2012. DESCOVY FOR PrEP® was approved in October 2019.[8]

When prescribing a potential long-term medication, such as PrEP, consider that[9]:

- Renal function may change over time
- Bone density is crucial for individuals of any age

62% of oral PrEP users had ≥1 renal risk factor[9]

(Retrospective US observational study, Jan 2015-Feb 2020; N=40,621)

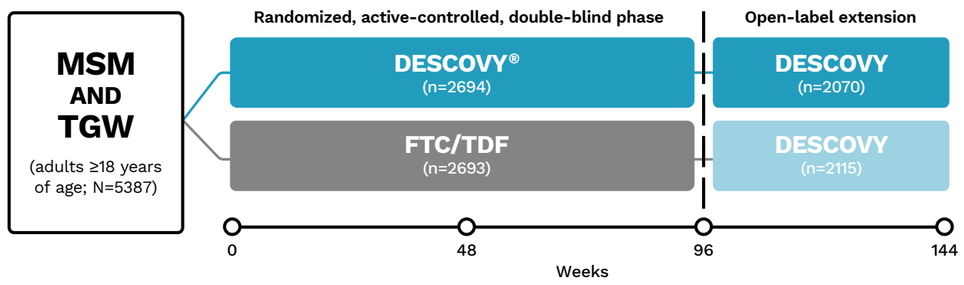
68% of oral PrEP users had ≥1 bone risk factor[9]

(Retrospective US observational study, Jan 2015-Feb 2020; N=40,621)

FDA=US Food and Drug Administration; FTC/TAF=emtricitabine/tenofovir alafenamide; FTC/TDF=emtricitabine/tenofovir disoproxil fumarate.

DESCOVY FOR PrEP® was studied over 144 weeks in the DISCOVER Trial[1,10,11]

DISCOVER is a large PrEP clinical trial, with over 5300 participants



At entry and Q12W, participants were offered:

- Adherence counseling
- Prevention services (risk-reduction counseling, condoms)

Primary endpoint analysis (n=5335):

HIV incidence/100 PY when 100% of participants reached Week 48 and ≥50% reached Week 96. Secondary analysis was conducted when 100% of participants reached Week 96.

Analysis from baseline through 96 weeks (DESCOVY vs FTC/TDF)

- Includes participants from both study arms in the 1:1 randomized, active-controlled, double-blind phase, from baseline through 96 weeks
  - Participants received either DESCOVY or FTC/TDF once daily

Analysis from baseline to ≥144 weeks (DESCOVY)

- Includes participants who initiated DESCOVY at baseline, through 96 weeks in the double-blind phase, and voluntarily continued on DESCOVY during the unblinded, open-label extension phase for another 48 weeks or more
  - Participants received DESCOVY once daily

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)

MSM=men who have sex with men; PY=person-years; Q12W=every 12 weeks; TGW=transgender women (who have sex with men).

TRIAL DESIGN

Participants selected for inclusion had significant risk of acquiring HIV[1,10]

Baseline demographics	DESCOVY (n=2694)	FTC/TDF (n=2693)
Median age, years (IQR)	34 (28-43)	34 (28-44)
Sex/gender		
Cis male	2649	2664
TGW	45	29
Race		
White	2264	2247
Black[a]	240	234
Asian	113	120
Ethnicity		
Hispanic or Latino/x	635	683
Baseline HIV risk factors		
≥2 condomless anal sex partners, past 12 weeks	62%	60%
Rectal gonorrhea, past 24 weeks	10%	10%
Rectal chlamydia, past 24 weeks	13%	12%
Syphilis, past 24 weeks	9%	10%
Recreational drug use, past 12 weeks	67%	67%
Binge drinking[b]	23%	22%
Taking FTC/TDF at baseline	17%	16%

[a] Includes mixed Black race.
[b] ≥6 drinks ≥1 occasion, at least monthly.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Comprehensive management to reduce risks:** (cont'd)
  - **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

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

Descovy®
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IQR=interquartile range.

EFFICACY DATA

Powerful HIV prevention: 99.7% remained HIV negative with DESCOVY®[1,10]

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

DESCOVY (n=2670)		FTC/TDF (n=2665)
99.7%	vs	**99.4%**

of participants remained HIV negative at primary analysis and through 96 weeks

HIV incidence rate (DESCOVY vs FTC/TDF)

- **Primary endpoint analysis: 0.16/100 PY** vs **0.34/100 PY** (IRR=0.47; CI: 0.19-1.15)
  - Conducted when 100% of participants reached Week 48 and ≥50% reached Week 96
- **Baseline through 96-week analysis: 0.16/100 PY** vs **0.30/100 PY** (IRR=0.54; CI: 0.23-1.26)
  - Conducted when 100% of participants reached Week 96

Study outcomes were similar across subgroups of age, race, gender identity, and baseline FTC/TDF use.

Nearly all patients remained HIV negative over 144 weeks[11]

DESCOVY (n=2670)

99.6%

of participants remained HIV negative over 144 weeks

Analysis from baseline to over 144 weeks

- **HIV incidence rate: 0.13/100 PY**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Comprehensive management to reduce risks:** (cont'd)
  - **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

CI=confidence interval; IRR=incidence rate ratio.

Few seroconversions were observed[1,10,11]

Seroconversions from baseline to ≥96 weeks

DESCOVY (n=2670)

8

FTC/TDF (n=2665)[a]

15

Suspected baseline infections: **1** (**DESCOVY**) and **4** (**FTC/TDF**)

Seroconversions at other time points

- **Primary endpoint analysis: 7 (DESCOVY) vs 15 (FTC/TDF)**
  - Primary analysis: When 100% of participants reached Week 48 and ≥50% reached Week 96
- **Baseline to ≥144 weeks analysis:**
  - 2 additional seroconversions occurred in the DESCOVY arm (n=2070)
  - 1 additional seroconversion occurred in the initially assigned FTC/TDF arm (n=2115)
- Median intracellular drug levels were substantially lower in participants infected with HIV-1 at the time of diagnosis vs uninfected, matched control participants. Values for 1 participant in the DESCOVY arm are not available

Counsel individuals to strictly adhere to the 1 tablet, once-daily dosing schedule, as efficacy is strongly correlated with adherence.

[a] Seroconversion was observed in 1 person in the FTC/TDF arm with missing DBS sample at the visit of HIV-1 diagnosis; a DBS sample collected 7 weeks prior to the diagnosis showed TFV-DP levels, indicating high adherence at that time.

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

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

Descovy®
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DBS=dried blood spot; TFV-DP=tenofovir diphosphate.

SAFETY DATA

Long-term safety profile through 96 weeks[1,2,10-14]

Nearly all individuals stayed on DESCOVY® in the DISCOVER Trial

1% of participants discontinued DESCOVY FOR PrEP® (n=2694)

vs

2% of participants discontinued FTC/TDF (n=2693)

Adverse events reported in ≥2% of participants

	DESCOVY (n=2694)	FTC/TDF (n=2693)
Diarrhea	5%	6%
Nausea	4%	5%
Headache	2%	2%
Fatigue	2%	3%
Abdominal pain[a]	2%	3%

[a] Includes the following terms: abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain, and abdominal discomfort.

The DESCOVY FOR PrEP safety profile at ≥144 weeks was similar to data through 96 weeks.

Mean change in lipid values through Week 96[b]

		DESCOVY		FTC/TDF	
Lipid value	**Optimal level**	**Baseline (mg/dL)**	**Week 96 change**	**Baseline (mg/dL)**	**Week 96 change**
Total cholesterol (fasted)	~150 mg/dL	175	-2	176	-13
HDL cholesterol (fasted)	≥40 mg/dL[c]	51	-2	51	-4
LDL cholesterol (fasted)	~100 mg/dL	103	-1	103	-8
Triglycerides (fasted)	<150 mg/dL	108	+6	111	-7
Total-cholesterol-to-HDL ratio	<4.5	3.7	+0.1	3.7	0.0

- Total-cholesterol-to-HDL ratio was similar for DESCOVY and FTC/TDF
- Decreases from baseline were seen in LDL-C, HDL-C, and total cholesterol levels in both arms
- The DESCOVY arm had increases in triglycerides vs decreases in the FTC/TDF arm; however, both were still within the target level

[b] Participants were excluded from the study if they took lipid-modifying medications at study entry or initiated the medications during the study. Only participants with both baseline and post-baseline fasting values were included in the above data.

[c] Value reflects target for individuals assigned male at birth. For full guideline recommendations, see the 2018 AHA/ACC Multisociety Guideline on the Management of Blood Cholesterol.[14]

Mean levels of fasting lipids were mostly stable for those who were on DESCOVY over 144 weeks.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Comprehensive management to reduce risks:** (cont'd)
  - 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

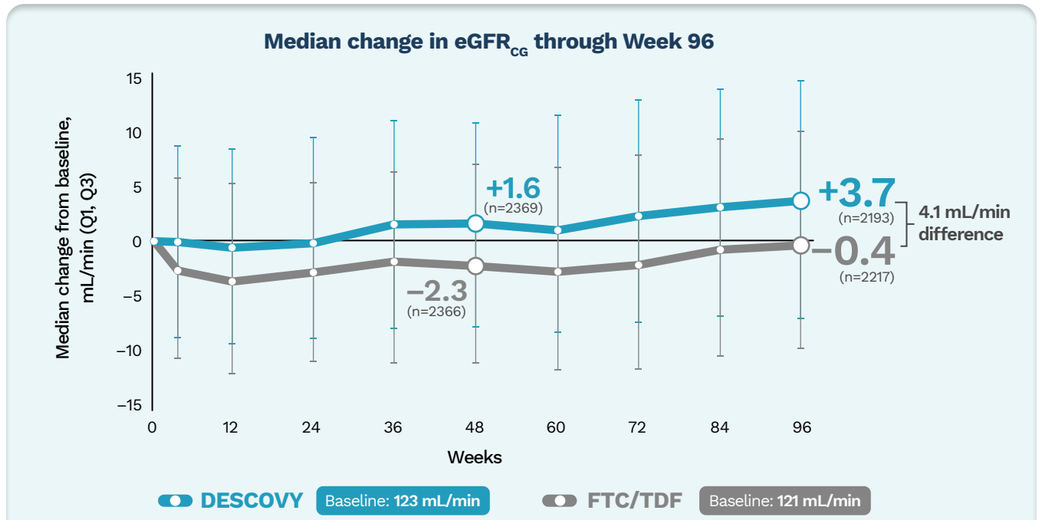
Please see full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING on risk of drug resistance with use of DESCOVY FOR PrEP in undiagnosed early HIV-1 infection and post-treatment acute exacerbation of hepatitis B**.

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

ACC=American College of Cardiology; AHA=American Heart Association; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol.

RENAL SAFETY DATA

DESCOVY® had less long-term impact on markers of renal function vs FTC/TDF[1,10]



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

IMPORTANT SAFETY INFORMATION (cont'd)

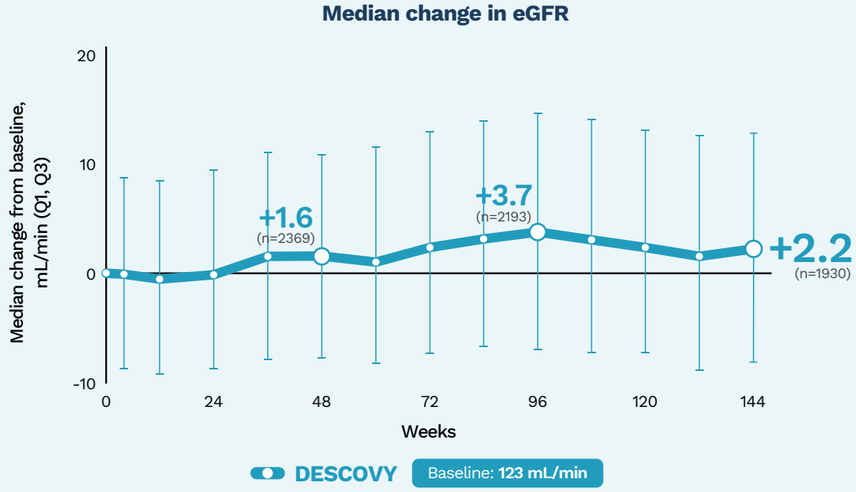
Warnings and precautions (cont'd)

- **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

eGFR=estimated glomerular filtration rate; eGFR$_{CG}$=estimated glomerular filtration rate using Cockcroft-Gault; Q1=first quartile; Q3=third quartile.

eGFR remained steady over 144 weeks with DESCOVY[1,11]

Analysis of eGFR from baseline to ≥144 weeks (DESCOVY)



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

DESCOVY FOR PrEP can be used in people with impaired renal function of CrCl ≥30 mL/min.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

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

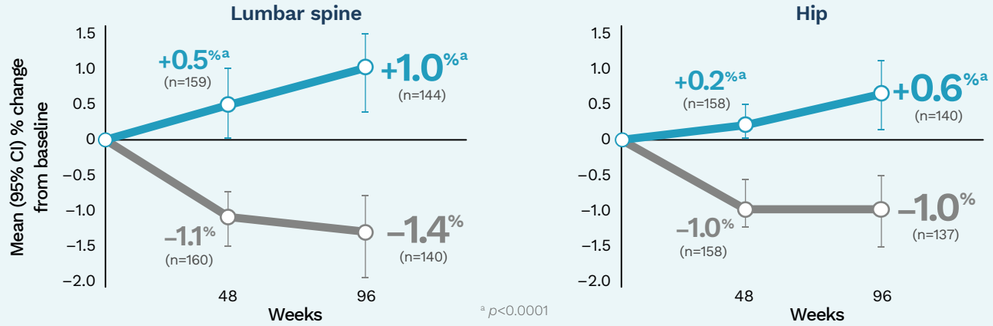
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tenofovir alafenamide 25mg tablets
for PrEP pre-exposure prophylaxis

CrCl=creatinine clearance.

Significantly less impact on BMD[1,10,11]

24% to 29% of participants in this substudy had osteopenia or osteoporosis at baseline



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

- 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.

BMD declines by site

- **≥5% at lumbar spine:** 4% in both treatment arms at Week 48; **4%** (**DESCOVY**) and **16%** (**FTC/TDF**) at Week 96
- **≥7% at total hip:** 1% in both arms at Week 48; **0%** (**DESCOVY**) and **1%** (**FTC/TDF**) at Week 96

People may be staying on PrEP long term. Consider BMD when prescribing a PrEP medication.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

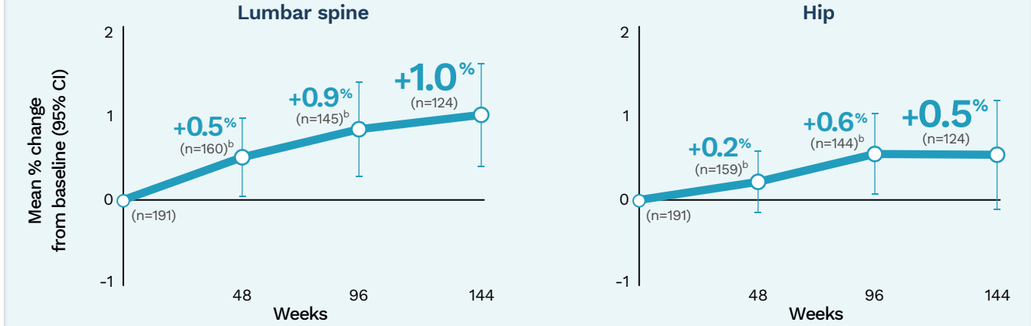
- **Prescribing information:** Consult the full Prescribing Information for DESCOVY for more information, warnings, and potentially significant drug interactions, including clinical comments
- **Metabolism:** Drugs that inhibit P-gp can increase the concentrations of TAF, a component of DESCOVY. Drugs that induce P-gp can decrease the concentrations of TAF, which may lead to loss of efficacy

BMD=bone mineral density; DXA=dual-energy X-ray absorptiometry.

BMD SAFETY DATA

Changes in BMD were consistent over 144 weeks[1,2]

A separate analysis of this substudy from baseline to ≥144 weeks (DESCOVY, n=191)



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

b Due to timing of the analysis and participant visits, 1 additional participant was included in the 144-week analysis.

Changes in BMD over 144 weeks were consistent with 96-week data.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

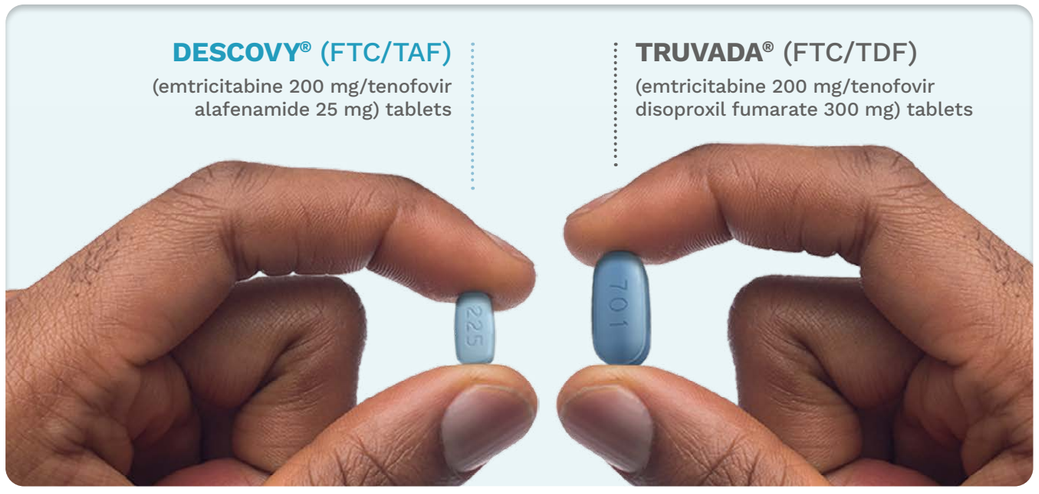
- **Drugs affecting renal function:** Coadministration of DESCOVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions

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

Get started with the smallest pill for daily oral PrEP[1,2,15]

Simple dosing, oral administration, and same-day start may be an option upon confirmation of HIV-negative test result



Pills shown are not actual size. DESCOVY actual size is 13 mm W x 6 mm H x 4 mm D. TRUVADA actual size is 19 mm W x 9 mm H x 7 mm D.

Please see full Prescribing Information for **TRUVADA**, including **BOXED WARNING**.

225 **One pill, once daily**

No food requirements

Same-day start
May be started same day upon confirmation of HIV-negative test result

DESCOVY Packaging	NDC Number[1]
Bottle	**61958-2002-1**

IMPORTANT SAFETY INFORMATION (cont'd)

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

NDC=National Drug Code.

DOSING/ADVANCING ACCESS

Advancing Access® is more than a co-pay card

Live support is available for eligible individuals

Benefits investigation
Program will help research and verify the individual's insurance coverage for their prescribed Gilead medication and receive information on in-network pharmacy restrictions.

Prior Authorization information
Program provides information if individual's insurance company requires the completion of a Prior Authorization for Gilead medication.

Medication Assistance Program
If individuals lack insurance coverage and meet the program criteria, they may be eligible to receive Gilead medication free of charge.

Co-pay support
The Gilead Co-pay Savings Program may help eligible, commercially insured individuals lower their out-of-pocket costs.[a] People enrolled in government prescription drug programs, such as Medicare Part D and Medicaid, are not eligible for the co-pay coupon. Restrictions may apply. Subject to change.

Advancing Access specialists can help provide insurance information support, including determining prior authorization and appeals process requirements, and connecting people to available resources to help them navigate coverage.

They can also help individuals prescribed DESCOVY to understand and navigate health insurance and Gilead medication costs. For more information, you can direct individuals to visit GileadAdvancingAccess.com or call 1-800-226-2056.

More patients now pay $0 out of pocket for DESCOVY FOR PrEP® than for generic FTC/TDF, regardless of insurance[2,a]

[a] Based on 2025-2026 out-of-pocket claims comparison. Prior to application of secondary benefits. Source: IQVIA LAAD Weekly, 01/01/2025 through 04/01/2026.

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

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The USPSTF has given PrEP medications—like DESCOVY®—a Grade A recommendation[16]

Over 98% of Gilead Advancing Access® Co-pay Savings Program users pay $0 each month for DESCOVY FOR PrEP®.[2,a,b]

Learn more at DESCOVYHCP.com



OF REAL-WORLD EXPERIENCE[1]



DAILY ORAL PrEP by HIV specialists[2]

Source: IQVIA® LAAD Weekly, 01/01/2020 through week ending (WE) 05/29/2026.[c]

>9 MILLION PRESCRIPTIONS WRITTEN SINCE FDA APPROVAL[2]

Source: IQVIA LAAD Weekly, DESCOVY FOR PrEP launch through WE 05/27/2026.[c]

[a] Co-pay Savings Program support is available for eligible, commercially insured patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit GileadAdvancingAccess.com/copay-coupon-card. This is not health insurance.
[b] Source: Data on file; as of 05/31/2026.
[c] This information is an estimate derived from the use of information under license from the following IQVIA information service: IQVIA Longitudinal and Adjudication Data from DESCOVY FOR PrEP WE 01/01/2020 through WE 05/29/2026 and launch through WE 05/27/2026. IQVIA expressly reserves all rights, including rights of copying, distribution and republication.

USPSTF=US Preventive Services Task Force.

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 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.**

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