



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

#### Long-term results over 144 weeks<sup>1-4</sup>

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

Baseline to ≥144 weeks analysis: **DESCOVY** participants in double-blind phase entering an additional ≥48-week OLE (n=2070).

## Noninferior HIV incidence rate through 96 weeks<sup>1-4</sup>

At primary analysis\*: **0.16/100 PY** vs **0.34/100 PY** 

At 96 weeks<sup>†</sup>: **0.16/100 PY** vs **0.30/100 PY** 

**99.7%** vs **99.4%** of participants remained **HIV negative** at both time points.

At ≥144 weeks: **0.14/100 PY; 99.5%** of individuals remained **HIV negative** with **DESCOVY**.

#### Safety profile through 144 weeks<sup>1,2,4</sup>

At 96 weeks: **Adverse reactions** (all grades) reported in ≥2% of participants **were similar in both study arms**, with few discontinuations due to adverse events (**1%** vs **2%**).

At ≥144 weeks: Safety profile **similar to ≥96 weeks** 

\*When 100% of participants reached Week 48 and ≥50% reached Week 96.

emtricitabine 200mg/

Descovy

tenofovir alafenamide 25mg tablets

for **PrEP** pre-exposure prophylaxis

<sup>+</sup>When 100% of participants reached Week 96.

#### **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<sup>®</sup>. 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**.

CLINICAL TRIAL DESIGN

EFFICACY DATA

RENAL SAFETY DATA

SAFETY DATA

# **Considerations for key populations**

Black and Latinx people are disproportionately underprescribed PrEP, based on 2022 CDC estimates<sup>5</sup>



PrEP coverage, reported as a percentage of persons aged ≥16 years, is calculated as the number having been prescribed PrEP divided by the estimated number who had indications for PrEP, as reported by the CDC through December 2022.



## PrEP use can be long term<sup>6,7</sup>



A real-world study looked at ~14,000 people\* who received PrEP care during a 6-year period (July 2012-March 2019; N=13,906)

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

- 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) \*Prescriptions were filled for FTC/TDF or FTC/TAF for individuals aged ≥18 years with an indication for PrEP.



PrEP was first approved by the FDA in 2012. **DESCOVY FOR PrEP®** was approved in October 2019.

# **Consider risk factors\* that may impact BMD** and renal function







Behavioral factors<sup>10,14,27-32</sup> Anabolic steroid use **Excessive alcohol consumption** Smoking Stimulant use

Concomitant medications<sup>22,33-36</sup> **NSAIDs Proton pump inhibitors GLP-1RAs** 

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CDC=Centers for Disease and Control and Prevention; FTC/TAF=emtricitabine/tenofovir alafenamide; FTC/TDF=emtricitabine/tenofovir disoproxil fumarate

\*Not an exhaustive list of all known risk factors that may affect BMD and renal function ADHD=attention-deficit/hyperactivity disorder; BMD=bone mineral density; CKD=chronic kidney disease; GLP-1RA=glucagon-like peptide-1 receptor agonist NSAID=nonsteroidal anti-inflammatory drug; TGW=transgender women (who have sex with men).





## Comorbidities<sup>24-26</sup>

Osteopenia/osteoporosis

(Younger males)

Low BMD (TGW)



Comorbidities<sup>37-46</sup>

**CKD or declining renal function** Comorbidities in adolescents **Diabetes** 

Hypertension • Obesity



EFFICACY DATA

ADHERENCE AND SAFETY DATA

RENAL SAFETY DATA

BMD SAFETY DATA

# **DESCOVY FOR PrEP®** was studied over 144 weeks in the DISCOVER Trial<sup>1-4,47</sup>

## DISCOVER is the largest 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 over 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
- Data for participants who switched from FTC/TDF, after 96 weeks in the blinded phase, to DESCOVY in the open-label extension phase are not shown

#### **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)

# **Participants selected for** had significant risk of ac

Baseline demographics	<b>DESCOVY</b> (n=2694)	<b>FTC/TDF</b> (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 <sup>a</sup>	240	234
Asian	113	120
Ethnicity		
Hispanic or Latino/x	635	683
Baseline HIV risk factors		
≥2 condomless anal sex partners, past 12 weeks	<b>62</b> %	<b>60</b> %
Rectal gonorrhea, past 24 weeks	10%	<b>10</b> %
Rectal chlamydia, past 24 weeks	13%	<b>12</b> %
Syphilis, past 24 weeks	9%	<b>10</b> %
Recreational drug use, past 12 weeks	<b>67</b> %	<b>67</b> %
Binge drinking <sup>b</sup>	<b>23</b> %	<b>22</b> %
Taking FTC/TDF at baseline	17%	<b>16</b> %

#### **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 full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING.**

<sup>a</sup> Includes mixed Black race. <sup>b</sup>≥6 drinks ≥1 occasion, at least monthly FTC/TDF=emtricitabine/tenofovir disoproxil fumarate; IQR=interquartile range; TGW=transgender women (who have sex with men).

inclusion	
quiring HIV <sup>1,2</sup>	9

(28-43)	34 (28-44)





BMD SAFETY DATA DOSING/ADVANCING ACCESS

# **Powerful HIV prevention: 99.7% remained** HIV negative with DESCOVY®<sup>1,2,4,47</sup>

## **DESCOVY FOR PrEP®** was noninferior to FTC/TDF 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.



#### **OF PARTICIPANTS REMAINED HIV NEGATIVE** AT PRIMARY ANALYSIS AND THROUGH 96 WEEKS

Actor portravals

#### HIV incidence rate with DESCOVY FOR PrEP was similar over 144 weeks<sup>3,4</sup>

#### HIV incidence rate (DESCOVY)

#### • Baseline to over 144 weeks analysis: 0.14/100 PY

- HIV incidence rate was calculated once participants, who were using DESCOVY at baseline in the 96-week randomized, double-blind phase, had completed at least 48 weeks in the open-label extension phase

#### **DESCOVY** (n=2070)

#### **OF PARTICIPANTS REMAINED HIV NEGATIVE** OVER 144 WEEKS

#### **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
- 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

# Few seroconversions were observed<sup>1,2,4,48,49</sup>

#### Seroconversions from baseline to ≥96 weeks

**DESCOVY (n=2670)** 

FTC/TDF (n=2665)\*



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: 3 additional seroconversions occurred in the DESCOVY arm (n=2070)
- 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



#### Efficacy is strongly correlated with adherence.

\*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. High adherence was defined as  $\geq$ 900 fmol/punch, which correlates to approximately  $\geq$ 4 pills a week.

#### **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

#### Please see full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING.**





for **PrEP** pre-exposure prophylaxis

KEY POPULATIONS/ PREP DURATION/ BONE AND RENAL RISK FACTORS CLINICAL TRIAL DESIGN EFFICACY DATA ADHERENCE AND SAFETY DATA RENAL SAFETY DATA

BMD SAFETY DATA

High adherence rates of DESCOVY® were observed among a randomly selected subset through the primary endpoint in the DISCOVER Trial<sup>1,48,49,\*</sup>



\*Primary endpoint: When 100% of participants reached Week 48 and ≥50% reached Week 96.

#### **DBS adherence analysis:**

- A subset of DISCOVER Trial participants (n=total number of participants) were randomly selected
- Adherence was evaluated by quantifying tenofovir diphosphate concentration in DBS at each post-baseline visit
- High adherence was defined as  $\geq$ 900 fmol/punch, which correlated to approximately  $\geq$ 4 pills a week

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

#### **IMPORTANT SAFETY INFORMATION** (cont'd)

#### Warnings and precautions (cont'd)

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

# **Demonstrated long-term safety profile** through 96 weeks<sup>1,2,29,49-51</sup>



## Adverse reactions (all grades) reported in ≥2% of participants

	<b>DESCOVY</b> (n=2694)	<b>FTC/TDF</b> (n=2693)
Diarrhea	<b>5</b> %	<b>6</b> %
lausea	<b>4</b> %	<b>5</b> %
leadache	2%	<b>2</b> %
atigue	<b>2</b> %	<b>3</b> %
Abdominal pain or discomfort	2%	<b>2</b> %

#### Mean change in lipid values through Week 96<sup>a</sup>

		DESC	COVY®	FTC	/TDF
Lipid value	Optimal level	<b>Baseline</b> (mg/dL)	Week 96 change	<b>Baseline</b> (mg/dL)	Week 96 change
Total cholesterol (fasted)	~150 mg/dL	175	-2	176	-13
HDL cholesterol (fasted)	≥40 mg/dL*	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

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. \*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.5



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

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.

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of participants discontinued FTC/TDF (n=2693)





CLINICAL TRIAL DESIGN

EFFICACY DATA

ADHERENCE AND SAFETY DATA

RENAL SAFETY DATA

BMD SAFETY DATA

# **DESCOVY®** had less long-term impact on markers of renal function vs FTC/TDF<sup>1,2</sup>



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

#### **Adverse reactions**

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

# with **DESCOVY**<sup>1,4</sup>





Please see full Prescribing Information for **DESCOVY FOR PrEP**, including **BOXED WARNING.** 



## Significantly less impact on BMD<sup>1,2,24,29</sup>

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

Mean % change in lumbar spine and hip BMD at Weeks 48 and 96 by DXA scans



#### 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
- **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

# Changes in BMD were consistent over 144 weeks<sup>1,4</sup>

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



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

<sup>a</sup>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.<sup>1,4,29</sup>

Please see full Prescribing Information for <u>**DESCOVY FOR PrEP**</u>®, including **BOXED WARNING**.





DOSING/ADVANCING ACCESS

BMD SAFETY DATA

# **DESCOVY®** is the smallest pill for PrEP<sup>47,49,53</sup>

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.



IMPORTANT	' SAFETY	INFORMATION	(cont'd)
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#### **Dosage and administration**

• Dosage: One tablet (emtricitabine 200 mg/tenofovir alafenamide 25 mg) taken once daily with or without food

DESCOVY Packaging

Bottle

**DESCOVY®** 

DayTracker™ pack

NDC Number<sup>1</sup>

61958-2002-1

61958-2002-2

- 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

#### Please see full Prescribing Information for **DESCOVY FOR PrEP**<sup>®</sup>, including **BOXED WARNING**

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

## Advancing Access<sup>®</sup> 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 Coupon Card may help eligible, commercially insured individuals lower their out-of-pocket costs.\* 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.

\* Eligible, commercially insured individuals enrolled in the Gilead Advancing Access Co-pay Coupon Card program could pay as little as \$0 co-pay. Uninsured individuals can contact Gilead's Advancing Access program for information about support options. Restrictions apply. Subject to change See full terms and conditions at GileadAdvancingAccess.com/hcp.

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KEY POPULATIONS/ PREP DURATION/ BONE AND RENAL RISK FACTORS CLINICAL TRIAL DESIGN EFFICACY DATA ADHERENCE AND SAFETY DATA RENAL SAFETY DATA BMD SAFETY DATA DOSING/ADVANCING ACCESS

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

# Learn more at **DESCOVYHCP.com**

Source: Data on File; as of 10/31/2023.

#### **INDICATION & LIMITATION OF USE**

DESCOVY<sup>®</sup> for HIV-1 pre-exposure prophylaxis (PrEP) is indicated in at-risk adults and adolescents ( $\geq$ 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 on previous pages 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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