



IS YOUR HIV PrEP COVERAGE MEETING THE NEEDS OF ALL APPROPRIATE MEMBERS AT RISK?

INDICATION

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 patients 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 patients 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 patients with HBV who discontinue DESCOVY. If appropriate, anti-hepatitis B therapy may be warranted

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including BOXED WARNING.

Even though PrEP is a proven strategy, it is underutilized

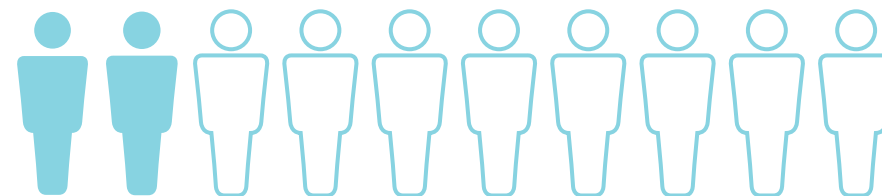
In the PROUD study, immediate PrEP initiation has been shown to lower HIV risk^{1,*}

Those who started PrEP immediately were

nearly 8x less likely

to acquire HIV than those who did not start immediately

- This study was an open-label, randomized trial conducted at 13 sexual health clinics in England. Enrollment included 544 HIV-negative, at-risk gay and other MSM. Participants were randomly assigned (1:1) to daily PrEP either immediately or after a deferral period of 1 year



PrEP medication is used by just 2 in 10 at risk²

In the US, of those indicated for PrEP, Hispanic/Latinx and Black populations are most at risk of HIV, yet few were using a PrEP medication^{3,4}:

10.9%
Hispanic/Latinx

5.9%
Black

*PROUD was conducted between 2012 and 2014. DESCOVY FOR PrEP was approved in 2019.
MSM = men who have sex with men.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindication

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

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

Every new HIV infection has costly long-term implications

Mean all-cause annual healthcare costs
from ages 25 to 69 were almost

7x higher

for PLWH compared to non-HIV population⁵

Avoiding one new HIV infection
can result in an average savings of

\$850,557

in lifetime healthcare costs⁵

- This is one of the first US studies to examine annual and cumulative costs in a large, real-world cohort of commercially insured PLWH compared with a population without HIV
- While cumulative all-cause cost estimates only approximate total cost burden for any given patient, the results may not be generalizable to all population subgroups
- Annual costs from 2013 to 2017 and projected cumulative costs of HIV from age 25 to 69 years were evaluated. Cumulative all-cause costs were derived from the health plan

From a retrospective, multiyear, cross-sectional analysis using IQVIA's commercial claims database.⁵

PLWH = people living with HIV.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP®](#), including **BOXED WARNING**.

Prevention is one of the key strategies for reaching the goals of *Ending the HIV Epidemic: A Plan for America*⁶



DIAGNOSE

all people with HIV
as early as possible



TREAT

HIV rapidly
and effectively to
achieve sustained
viral suppression



PREVENT

new HIV transmissions by
using proven interventions,
including pre-exposure
prophylaxis (PrEP) and syringe
services programs (SSPs)



RESPOND

quickly to potential
HIV outbreaks to get
prevention and treatment
services to people
who need them

PrEP medication is a critical component of comprehensive HIV prevention.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Comprehensive management to reduce risks:**

- Use DESCOPY 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

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOPY FOR PrEP](#), including **BOXED WARNING**.

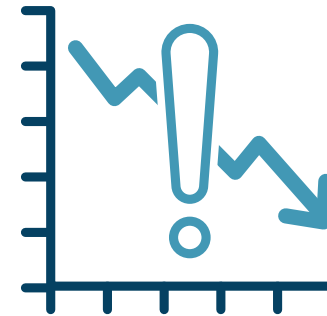
USPSTF and ACA have taken steps to elevate the need for clinically appropriate PrEP medications

Grade A—PrEP received USPSTF's highest recommendation⁷

With its latest recommendations, the US Preventive Services Task Force (USPSTF) concluded with high certainty that the net benefit of using PrEP medication to reduce the risk of HIV infection is substantial.



Based on this recommendation, the ACA requires most private health plans, Medicaid expansion plans, and traditional Medicaid plans* to cover PrEP medications **without cost-sharing to clinically appropriate individuals.**^{8,9}



It's important to leave PrEP decisions to healthcare providers and their patients following PrEP clinical practice guidelines established by the CDC.¹⁰

In addition to assessing HIV risk, clinicians must consider safety, efficacy, and potential impact to overall health when prescribing a PrEP medication.

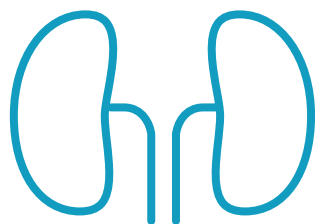
*Dependent on state policy.

ACA = Affordable Care Act; CDC = Centers for Disease Control and Prevention; USPSTF = US Preventive Services Task Force.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP®](#), including **BOXED WARNING.**

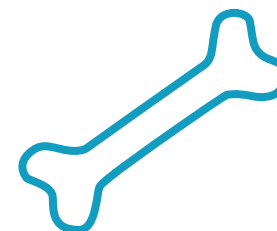
HIV risk does not discriminate—it affects sexually active individuals of all ages and can last throughout their lives¹¹

Safety, efficacy, and potential impact to overall health should be considered when choosing clinically appropriate PrEP medication



Renal exposure may matter more over time¹²⁻¹⁵

- Markers of renal function (eGFR and serum creatinine) can be affected by exposure to certain drugs
- GFR naturally declines over time with age
- African Americans and Hispanics are at greater risk for kidney failure than Caucasians



Bone density is crucial for individuals of any age¹⁶⁻¹⁸

- **Individuals under 30** are often still building bone
- **Individuals over 40** may already be experiencing BMD declines

BMD = bone mineral density, eGFR = estimated glomerular filtration rate; GFR = glomerular filtration rate.

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 patients 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 patients with undetected HIV-1 infection who are taking only DESCovy because DESCovy alone is not a complete regimen for treating HIV-1

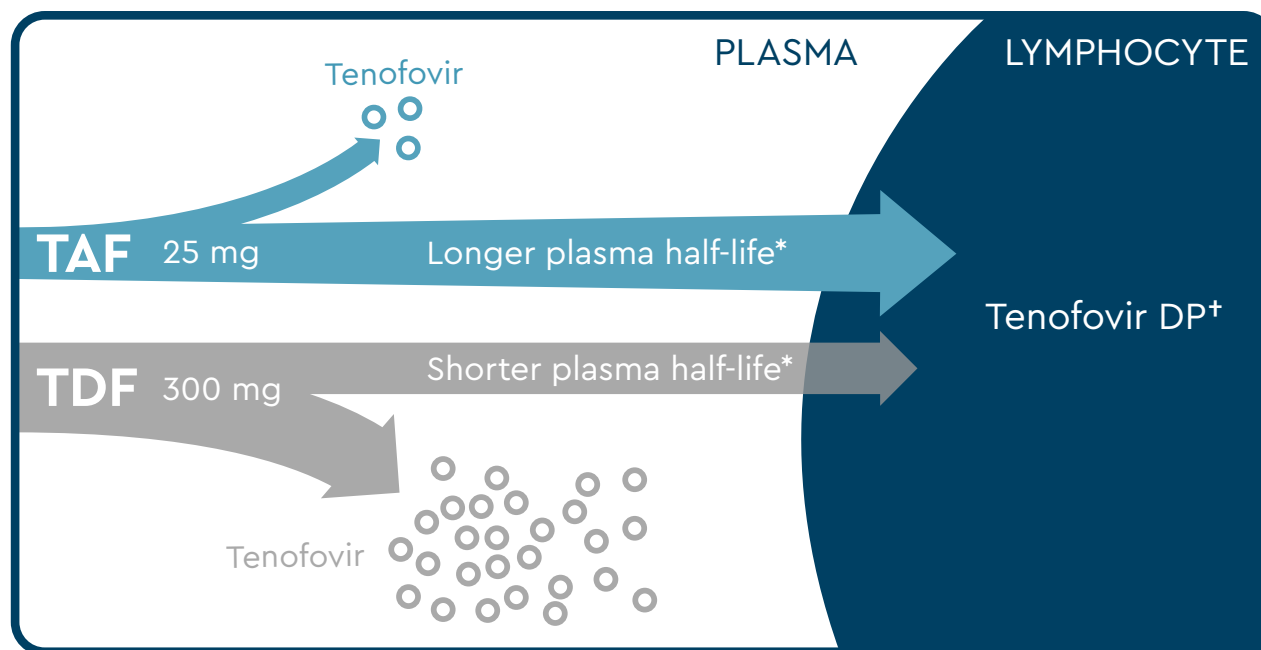
Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCovy FOR PrEP](#), including **BOXED WARNING**.



There is a difference between PrEP drug molecules

DESCOVY® contains TAF, which more efficiently delivers tenofovir DP into PBMCs (including lymphocytes like CD4+ T cells) and macrophages vs TDF¹⁹

- **Less tenofovir in plasma:** up to 90% reduction of tenofovir levels in plasma with TAF vs TDF^{20,21}
- **More targeted delivery of active drug:** up to 7x higher mean levels of tenofovir DP in lymphocytes are achieved with TAF vs TDF^{20,21}



*Plasma half-life: TAF = 30 minutes; TDF = 0.41 minutes.^{21,22}

†Tenofovir is converted into tenofovir DP in cells.¹⁹

DP = diphosphate; PBMCs = peripheral blood mononuclear cells (includes CD4+ T cells); TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

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

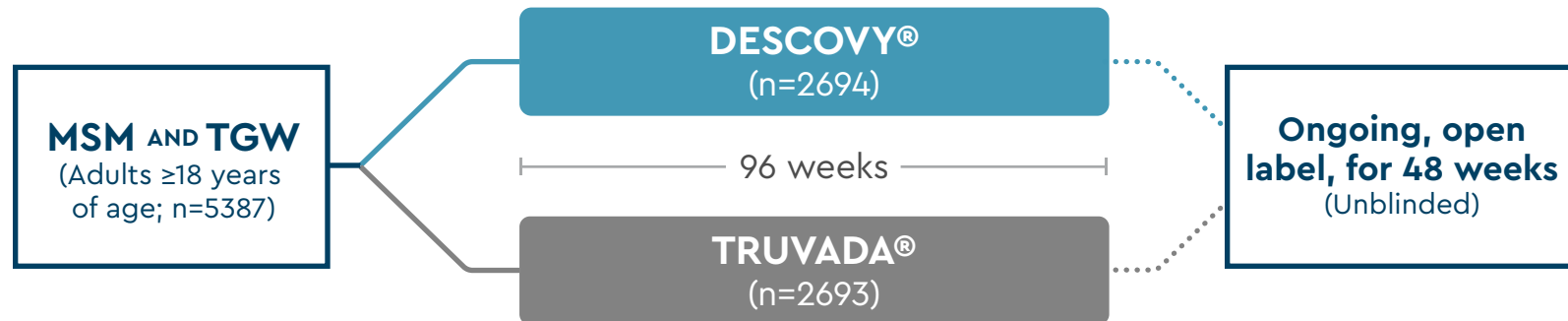
- Some HIV tests may not detect acute HIV infection. Prior to initiating DESCOVY FOR PrEP®, ask patients about potential recent exposure events. If recent (<1 month) exposures are reported or suspected, or symptoms of acute HIV infection (e.g., fever, fatigue, myalgia, skin rash) are present, confirm 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 click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

DISCOVERY was the largest PrEP head-to-head trial, with more than 5000 participants^{19,23-26}



Randomized, active-controlled, double-blind trial



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

A subset of the population included:

- 17% of participants who were using TRUVADA at baseline (n=897). Of these participants:
 - 51% were randomized to DISCOVERY for PrEP[®] (n=459)
 - 49% were randomized to continue using TRUVADA (n=438)

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

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 DISCOVERY FOR PrEP, convert the DISCOVERY 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 patients to strictly adhere to daily dosing, as efficacy is strongly correlated with adherence. Some patients, such as adolescents, may benefit from more frequent visits and counseling

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

DISCOVER trial eligibility required significant risk of acquiring HIV^{19,23,27}



Baseline demographics

	DESCOVY® (n=2694)	TRUVADA® (n=2693)
Median age, years (range)	34 (18-76)	34 (18-72)
Sex/gender		
Male	2649	2664
TGW	45	29
Race		
White	2264	2247
Black*	240	234
Asian	113	120
Ethnicity		
Hispanic or Latino	635	683

*Includes mixed Black race.

Baseline HIV risk factors, %

	DESCOVY (n=2694)	TRUVADA (n=2693)
≥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 [†]	23%	22%
Taking TRUVADA at baseline	17%	16%

[†]≥6 drinks on ≥1 occasion, at least monthly.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. Do not initiate DESCovy in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue DESCovy in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients (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

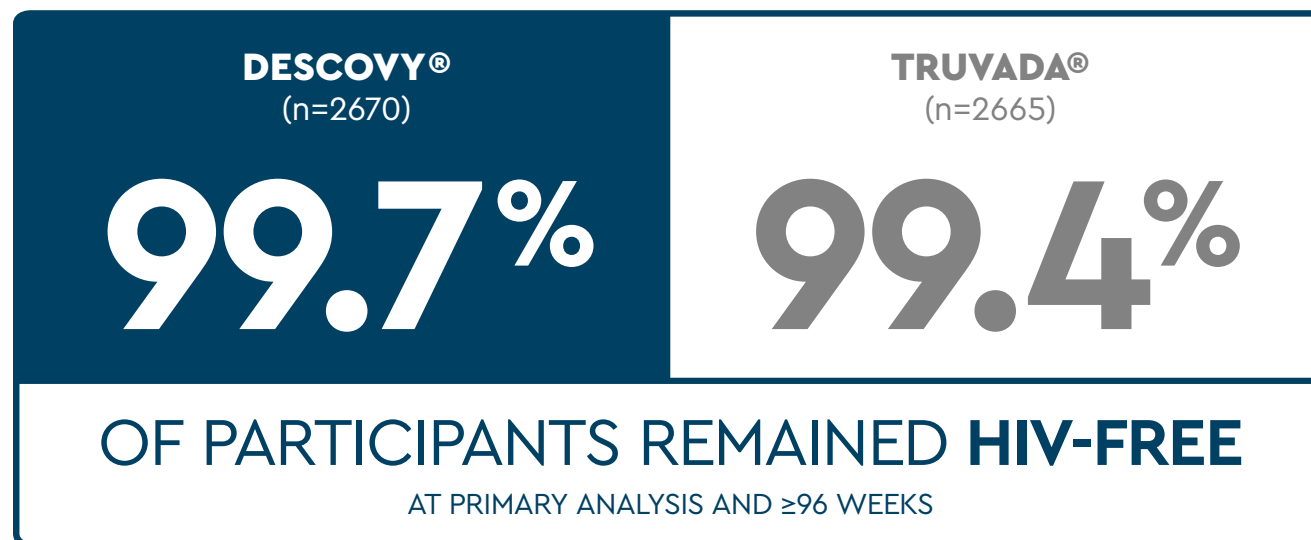
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Nearly all participants remained HIV-free through Week 96^{19,23}



DESCOVY FOR PrEP[®] was noninferior to TRUVADA

- HIV incidence rate of 0.16/100 PY for DESCOVY vs 0.34/100 PY for TRUVADA (IRR=0.47; CI: 0.19-1.15) at primary analysis
- HIV incidence rate of 0.16/100 PY for DESCOVY vs 0.30/100 PY for TRUVADA (IRR=0.54; CI: 0.23-1.26) at ≥ 96 weeks
- Primary analysis was assessed when 100% of participants reached Week 48 and $\geq 50\%$ reached Week 96



Treatment outcomes were similar across subgroups of age, race, gender identity, and baseline TRUVADA use.

IRR = incidence rate ratio.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

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

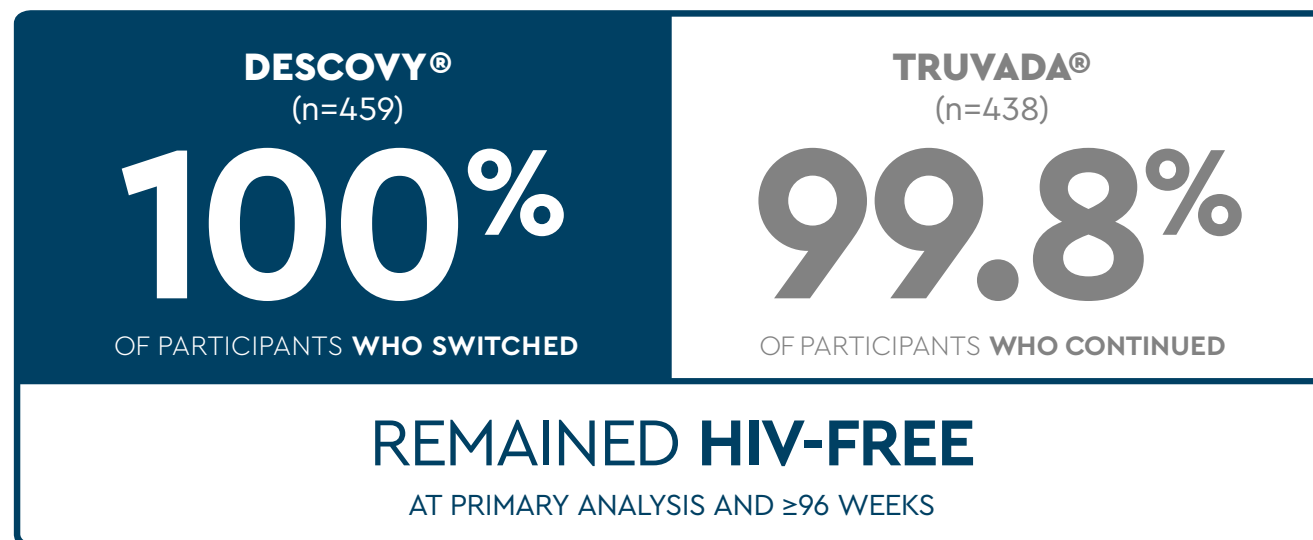
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Observed efficacy in switch subset^{19,23}

DESCOVY FOR PrEP[®] was noninferior to TRUVADA

- **Participants who switched:**
Participants who were using TRUVADA at baseline and randomized to DESCOVY FOR PrEP
- **Participants who continued:**
Participants using TRUVADA at baseline who were randomized to TRUVADA



IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

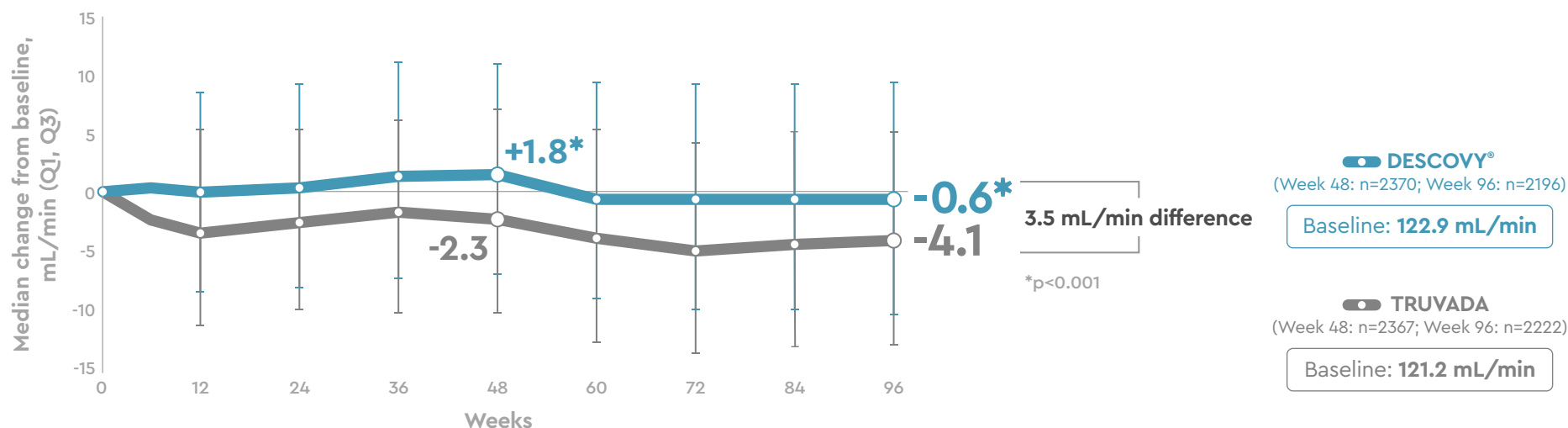
- **Prescribing information:** Consult the full Prescribing Information for DESCOVY for more information, warnings, and potentially significant drug interactions, including clinical comments
- **Metabolism:** Drugs that inhibit P-gp can increase the concentrations of tenofovir alafenamide (TAF), a component 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

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Less impact on markers of renal function^{19,23}

Median change in eGFR_{CG} through Week 96 vs TRUVADA®



- Lower serum creatinine levels were also seen with DESCOVY for PrEP® through Week 96
 - Mean serum creatinine decreased 0.01 mg/dL with DESCOVY FOR PrEP vs a 0.03 mg/dL increase with TRUVADA from baseline at Week 96

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

eGFR_{CG} = estimated glomerular filtration rate (Cockcroft-Gault); Q1, Q3 = first quartile, third quartile.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

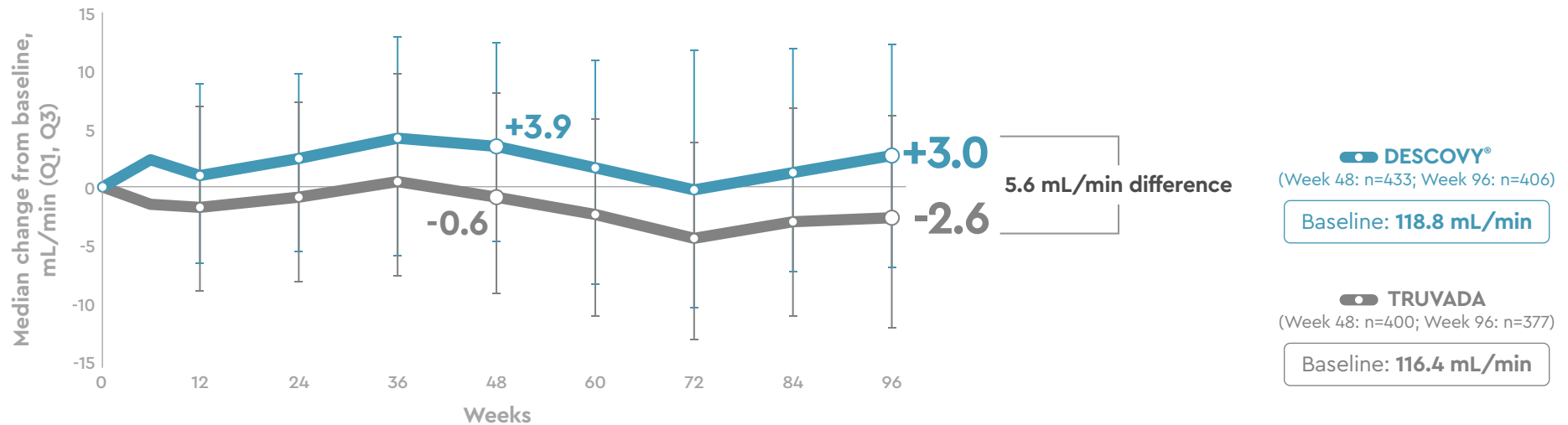
- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. Do not initiate DESCOVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue DESCOVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients (see Dosage and Administration section)

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A key marker of kidney function improved after switching^{19,23}



Median change in eGFR_{CG} through Week 96 vs TRUVADA®



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

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

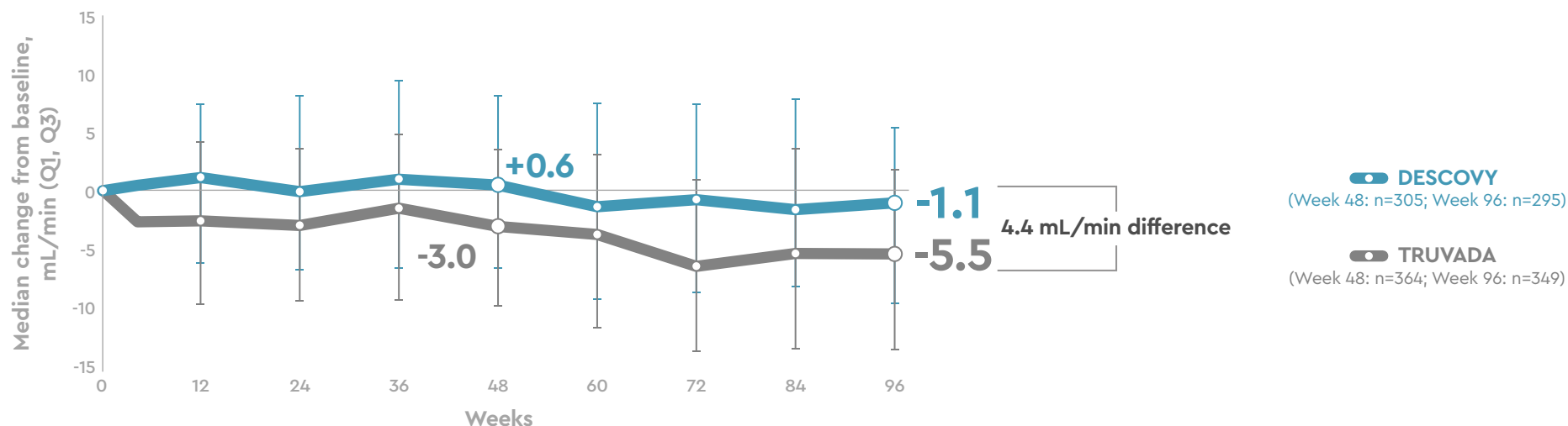
- **Dosage:** One tablet taken once daily with or without food
- **HIV screening:** Test for HIV-1 infection immediately prior to initiating, at least every 3 months during use, and upon diagnosis of an STI (see Warnings and Precautions section)
- **HBV screening:** Test for HBV infection prior to or when initiating DESCOVY
- **Renal impairment and monitoring:** Not recommended in patients with creatinine clearance (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 patients. In patients with chronic kidney disease, assess serum phosphorus

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP®](#), including **BOXED WARNING**.

Long-term reduced impact on eGFR over 96 weeks in participants ≥ 50 years of age^{13,19,28}



DESCOVY[®] had less impact on eGFR vs TRUVADA[®] in participants already experiencing age-associated declines



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

DESCOVY FOR PrEP[®] can be used in members with impaired renal function of CrCl ≥ 30 mL/min.

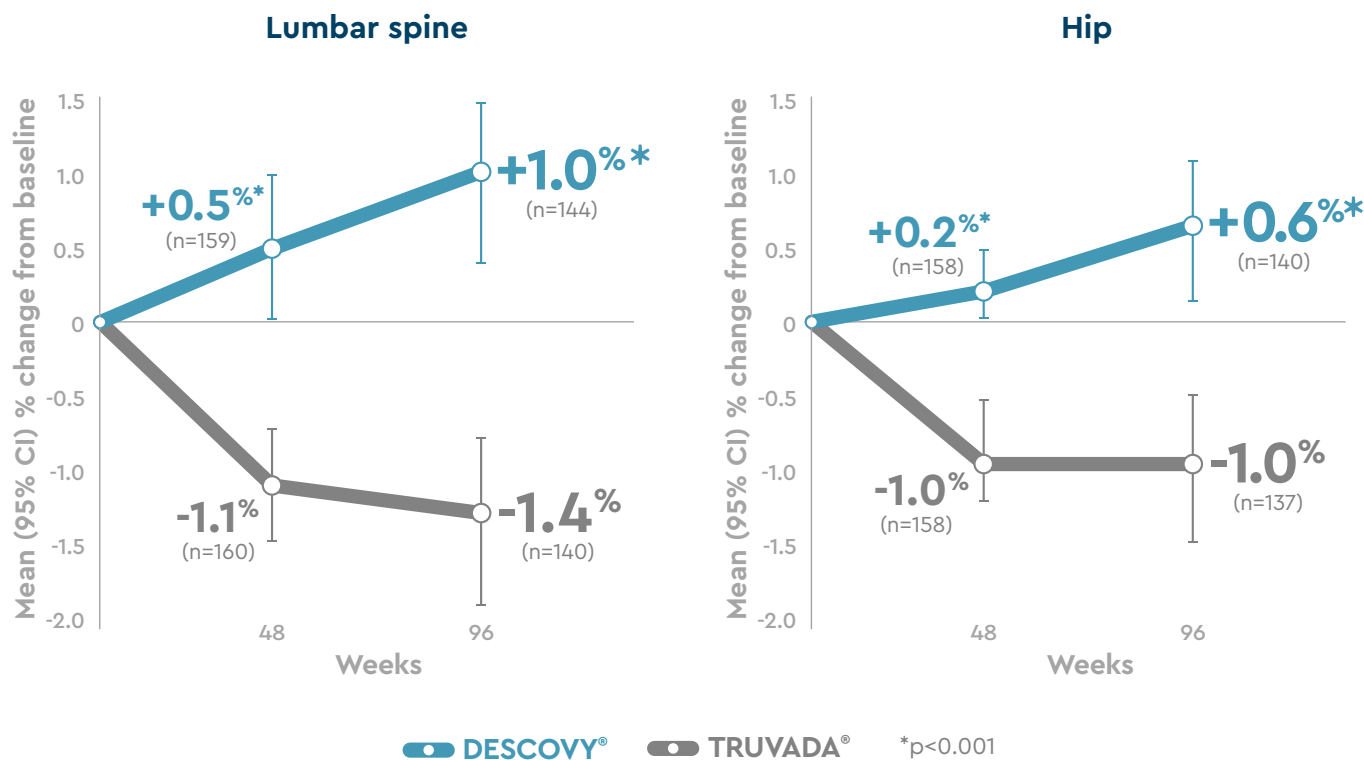
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Significantly less impact on bone mineral density (BMD)^{18,23,29,30}



Changes seen in both arms continued through Week 96

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



- **BMD declines of ≥5% at the lumbar spine** were experienced by 4% of participants in both treatment arms at Week 48, and **in 4% of DESCOVY participants and 16% of TRUVADA participants at Week 96**. **BMD declines of ≥7% at the total hip** were experienced by 1% in both treatment arms at Week 48, and **in 0% of DESCOVY participants and 2% of TRUVADA participants at Week 96**
- Analysis of these parameters was conducted in a subset of the study population (n=375)
- BMD was assessed at baseline, Week 48, and Week 96 by dual-energy X-ray absorptiometry (DXA) scans
- DESCOVY FOR PrEP® had less impact on BMD compared with TRUVADA. Increases in BMD observed in DISCOVER participants may be consistent with innate bone development

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

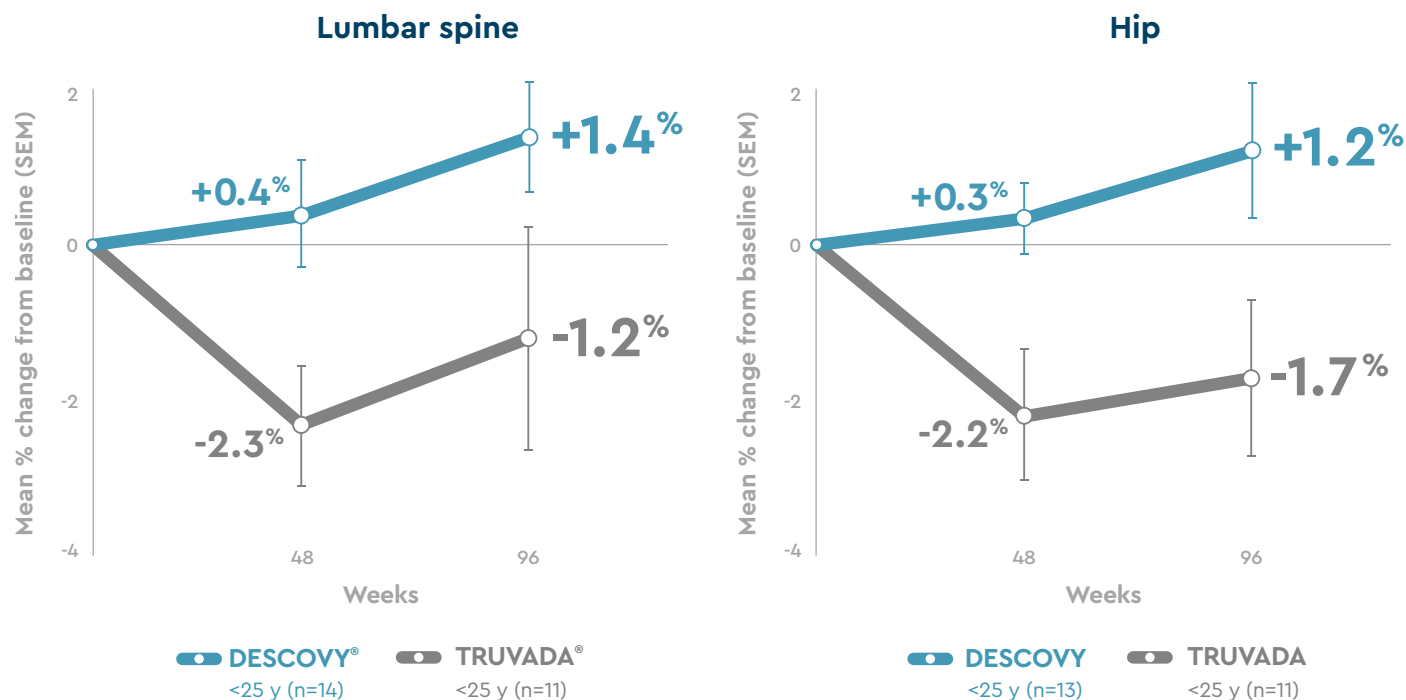
At baseline 24%-30% of DISCOVER participants had osteopenia or osteoporosis in the spine or hip.

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Long-term reduced impact on BMD over 96 weeks in participants <25 years of age^{16,17,28,31}



Males can continue to develop bone mass up to age 33, putting this age group at greater risk



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

Because members may be staying on a PrEP regimen for longer periods of time, consider a PrEP medication with BMD in mind.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP[®]](#), including **BOXED WARNING**.

Demonstrated long-term safety profile through Week 96^{19,23}



Few discontinuations due to adverse events

1%

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

VS

2%

of participants discontinued
TRUVADA®
(n=2693)

Adverse reactions (all grades) reported in $\geq 2\%$ of participants were similar for both study arms

	DESCOVY® (n=2694)	TRUVADA (n=2693)
Diarrhea	5%	6%
Nausea	4%	5%
Headache	2%	2%
Fatigue	2%	3%
Abdominal Pain	2%	3%

Mean changes from baseline in lipid values through Week 96

- Total-cholesterol-to-HDL ratio was similar for DESCOVY and TRUVADA (+0.1 mg/dL vs +0.0 mg/dL, respectively)
- Both DESCOVY and TRUVADA arms had decreases from baseline in LDL-C (-1 mg/dL vs -8 mg/dL, respectively), HDL-C (-2 mg/dL vs -4 mg/dL, respectively), and total cholesterol levels (-2 mg/dL vs -13 mg/dL, respectively)
- Triglycerides in the DESCOVY arm increased (+6 mg/dL) and decreased in the TRUVADA arm (-7 mg/dL); however, both were still within the desirable range

HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

Two packaging options, same wholesale acquisition cost

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



*Pills shown are not actual size.

DESCOVY[®] DayTracker[™] Pack

- Priced the same as bottles to allow patient preference to be taken into account
- Visually trackable doses with a helpful reminder built in

NDC 61958-2002-1

30 tablets in 1 bottle¹⁹

NDC 61958-2002-2

30 tablets in 1 blister pack¹⁹

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 patients 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 patients 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 patients with HBV who discontinue DESCOVY. If appropriate, anti-hepatitis B therapy may be warranted

Please see additional Important Safety Information throughout and click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

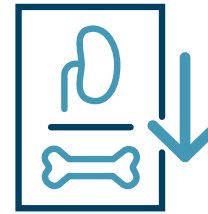


Another proven option to reduce HIV infection



Long-term efficacy
through Week 96^{19,23}

- HIV incidence rate of 0.16/100 PY for DESCOVY® vs 0.34/100 PY for TRUVADA® (IRR=0.47; CI: 0.19-1.15) at primary analysis*
- HIV incidence rate of 0.16/100 PY for DESCOVY vs 0.30/100 PY for TRUVADA (IRR=0.54; CI: 0.23-1.26) at ≥ 96 weeks
- 99.7% of participants using DESCOVY FOR PrEP® remained HIV-free vs 99.4% of participants using TRUVADA at both time points



Less impact on renal
parameters and BMD^{19,23}

- DESCOVY demonstrated less impact on select renal parameters compared to TRUVADA through Week 96
- DESCOVY demonstrated significantly less impact on BMD compared to TRUVADA through Week 96 (n=375)

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

Your Gilead account manager can help evaluate whether your HIV formulary meets the needs of appropriate members at risk.

*When 100% of participants reached Week 48 and $\geq 50\%$ reached Week 96.
IRR = incidence rate ratio.

INDICATION

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 click to see full Prescribing Information for [DESCOVY FOR PrEP](#), including **BOXED WARNING**.

References



- McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet*. 2016;387:53-60.
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