DYAD
Sponsored by ViiV Healthcare

BIKTARVY® vs DOVATO® (dolutegravir/lamivudine)

Head-to-Head Safety Data

Data From a Phase 4 Randomized, Open-Label Noninferiority Study
With Additional Safety Data From a Phase 3 BIKTARVY Study vs FTC/TAF+DTG[1-3]

People featured are compensated by Gilead.

BIKTARVY is the #1 prescribed regimen for 7 years* for people switching HIV-1 treatment. **Nearly 500,000 PWH in the US†** are on BIKTARVY.[4]

INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history; or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir; or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients with HIV-1 and HBV who have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients with HIV-1 and HBV who discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

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DTG, dolutegravir; FTC, emtricitabine; LAAD, Longitudinal Access and Adjudicated Data; PWH, people with HIV; TAF, tenofovir alafenamide.

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BIKTARVY® vs DOVATO® in VS PWH

DYAD: A US-Based Head-to-Head Study in VS PWH

Study design[1,5]

- A phase 4, single-center, open-label, noninferiority study, sponsored by ViiV Healthcare, that randomized 222 virologically suppressed adults (HIV-1 RNA <50 copies/mL) with no prior virologic failure (2:1) to switch to DOVATO (n=149) or continue on BIKTARVY (n=73)
- At Week 48, 134 PWH on DOVATO and 65 PWH on BIKTARVY completed the randomized phase of the study. Of these, 124 PWH on DOVATO and 63 PWH on BIKTARVY consented to participate in the observational extension phase
- The observational extension phase collected 96- and 144-week real-world efficacy and safety data from electronic medical records

Select exclusion criteria[1,5]

- HBV infection or acute need for HCV therapy
- History of prior virologic failure
- Suspected or documented INSTI resistance
- Major NRTI resistance

Primary endpoint[1]

- Proportion of participants with HIV-1 RNA ≥50 copies/mL at Week 48 using the FDA snapshot algorithm (ITT-E), 6% noninferiority margin
  - All randomized participants who received ≥1 dose of study treatment were included in the ITT-E population and used for efficacy and safety analyses

Select secondary endpoints[1,5]

- Proportion of participants with HIV-1 RNA <50 copies/mL at Week 48, 96, and 144 in the ITT-E population
- Safety and tolerability, including adverse events and laboratory tests (ie, renal, lipids, weight)

Select study limitation[6]

- Safety and tolerability, including adverse events, renal markers, lipids, and weight, were summarized using descriptive statistics. The clinical significance of these findings is unknown

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Primary endpoint results[1]

- Primary endpoint was met at Week 48: 4% in the DOVATO arm (n=6) and 7% in the BIKTARVY arm (n=5) had HIV-1 RNA ≥50 copies/mL (treatment difference, -2.8%; 95% CI, −11.4% to 3.1%)

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

CI, confidence interval; FDA, US Food and Drug Administration; HBV, hepatitis B virus; HCV, hepatitis C virus; INSTI, integrase strand transfer inhibitor; ITT-E, intent-to-treat–exposed; NRTI, nucleoside reverse transcriptase inhibitor; PWH, people with HIV; RNA, ribonucleic acid; VS, virologically suppressed.

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Select Baseline Participant Characteristics[1]

		BIKTARVY (n=73)	DOVATO (n=149)
Age, median (range), years		**51** (20–73)	**49** (24–73)
Age ≥50, n (%)		**44** (60)	**74** (50)
Sex: female, n (%)		**12** (16)	**24** (16)
Race, n (%)	Caucasian	**54** (74)	**102** (68)
	Black	**18** (25)	**44** (30)
	Asian	**0** (0)	**1** (1)
	Other	**1** (1)	**2** (1)
Hispanic/Latino, n (%)		**22** (30)	**43** (29)
Weight, median (range), kg		**88.5** (59.1–123.5)	**90.4** (53.1–171.9)
CD4+ T-cell count, median (range), cells/mm^3		**734.5** (151–1573)	**720.5** (214–1479)
Duration of ART prior to Day 1, median (range), years		**9.5** (1–27)	**12** (1–32)
Number of ART regimens prior to Day 1, median (range)		**3** (1–10)	**3** (1–9)

The majority of PWH were ≥50 years old (BIKTARVY 60%; DOVATO 50%)[1]

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ART, antiretroviral therapy; CD4, cluster of differentiation 4; PWH, people with HIV; VS, virologically suppressed.

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Drug-Related AEs and Withdrawals Through Week 96[1,5]

Drug-Related AEs Through Week 96

% (n)	Week 48*		Week 96†	
	BIKTARVY (n=73)	DOVATO (n=149)	BIKTARVY (n=73)	DOVATO (n=149)
Drug-related AEs	3% (2)	21% (31)	5% (4)	28% (42)
≥2% of either arm				
Nausea	0%	5% (7)	1% (1)	5% (8)
Fatigue	0%	4% (6)	0%	4% (6)
Diarrhea	0%	3% (5)	0%	4% (6)
Headaches	0%	3% (5)	0%	3% (5)
Insomnia	0%	3% (5)	1% (1)	4% (6)
Weight gain‡	-	-	0%	3% (4)
Worsening depression	0%	2% (3)	1% (1)	2% (3)
Dizziness‡	0%	2% (3)	-	-
Constipation‡	1% (1)	1% (2)	-	-
Proteinuria‡	1% (1)	0%	-	-
Light-headedness‡	-	-	0%	2% (3)
Drug-related AEs leading to withdrawal	0%	4% (6)§	0%	7% (11)‖

Safety and tolerability analyses were summarized using descriptive statistics. The clinical significance of these findings is unknown.[6]

*Week 48 results are from the randomized study.[1]
†Week 96 results are from the observational extension phase, which collected and reported efficacy and safety data from electronic medical records.[5]
‡A dash (-) indicates that AE was not reported to meet the threshold of ≥2% of either arm at that timepoint.[1,5]
§Drug-related AEs leading to withdrawal: neuropsychiatric complaints (4), pancreatitis (1), and nausea (1).[1]
‖Drug-related AEs leading to withdrawal: neuropsychiatric complaints (7), weight gain (2), pancreatitis (1), and nausea (1).[1]

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

AE, adverse event; PWH, people with HIV; VS, virologically suppressed.

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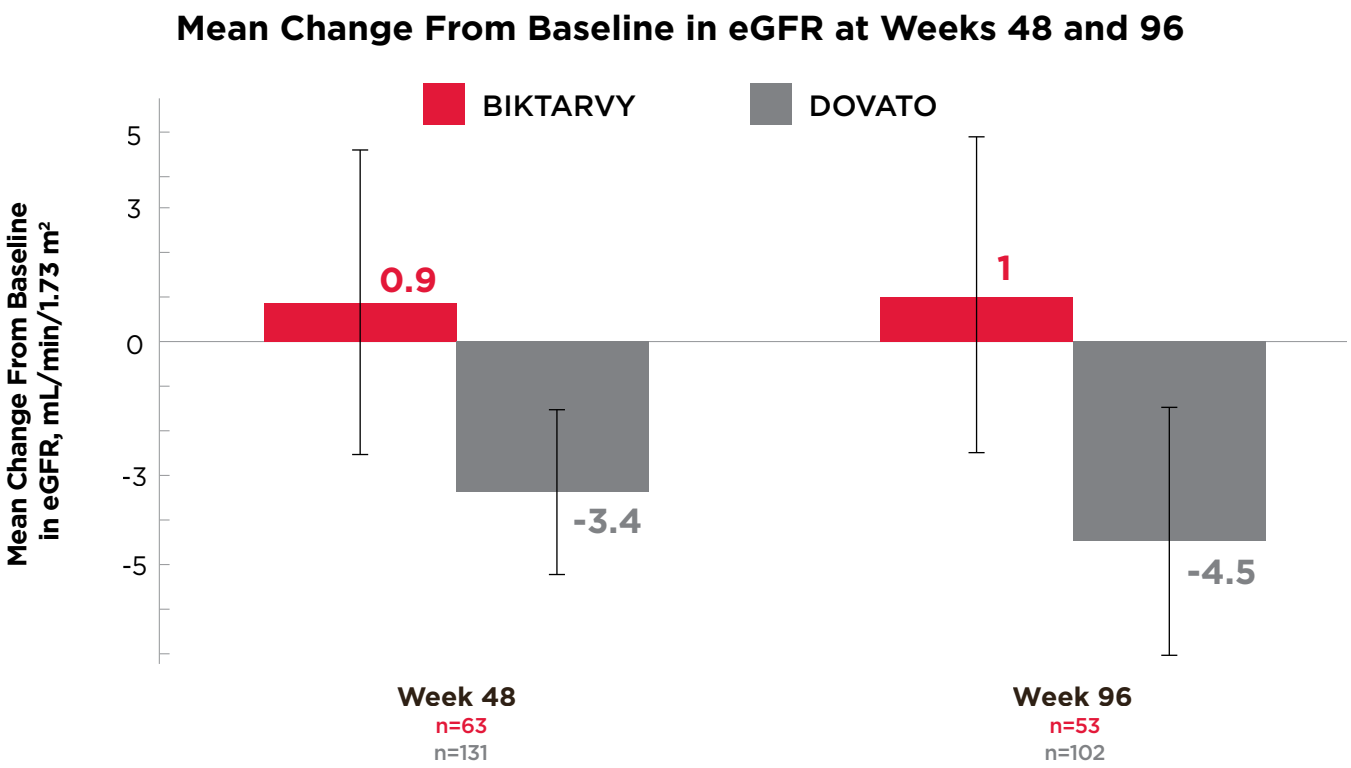
Mean Change From Baseline in eGFR at Weeks 48 and 96[1,5]



A descriptive analysis found a statistical difference in mean change from baseline in eGFR between BIKTARVY and DOVATO at Weeks 48 and 96

The long-term clinical significance of changes in eGFR is unknown[1,6]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **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 BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

eGFR, estimated glomerular filtration rate; PWH, people with HIV; VS, virologically suppressed.

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Mean Change From Baseline in Lipid Parameters at Weeks 48 and 96[1,5]

Mean Change From Baseline in Lipid Parameters at Weeks 48 and 96

	Week 48		Week 96	
	BIKTARVY (n=73)	DOVATO (n=149)	BIKTARVY (n=73)	DOVATO (n=149)
Total-C (mg/dL)	**+3.3** (n=62)	**-2.3** (n=130)	**-5.7** (n=51)	**-5.0** (n=92)
LDL-C (mg/dL)	**+1.4** (n=62)	**-3.0** (n=126)	**-6.0** (n=51)	**-5.5** (n=88)
HDL-C (mg/dL)	**+0.6** (n=62)	**+0.0** (n=130)	**-0.1** (n=51)	**-0.3** (n=92)
Triglycerides (mg/dL)	**+9.3** (n=62)	**+3.8** (n=130)	**+11.9** (n=51)	**+11.5** (n=92)
Total-C:HDL-C ratio	**-0.1** (n=41)	**-0.2** (n=82)	**-0.2** (n=35)	**-0.2** (n=55)

- At Week 48, hyperlipidemia occurred in 5% of PWH in the BIKTARVY arm and 4% of PWH in the DOVATO arm[1]
  - Initiation of lipid-lowering therapy occurred in 23% of PWH in the BIKTARVY arm and 12% of PWH in the DOVATO arm[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY 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** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

C, cholesterol; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PWH, people with HIV; VS, virologically suppressed.

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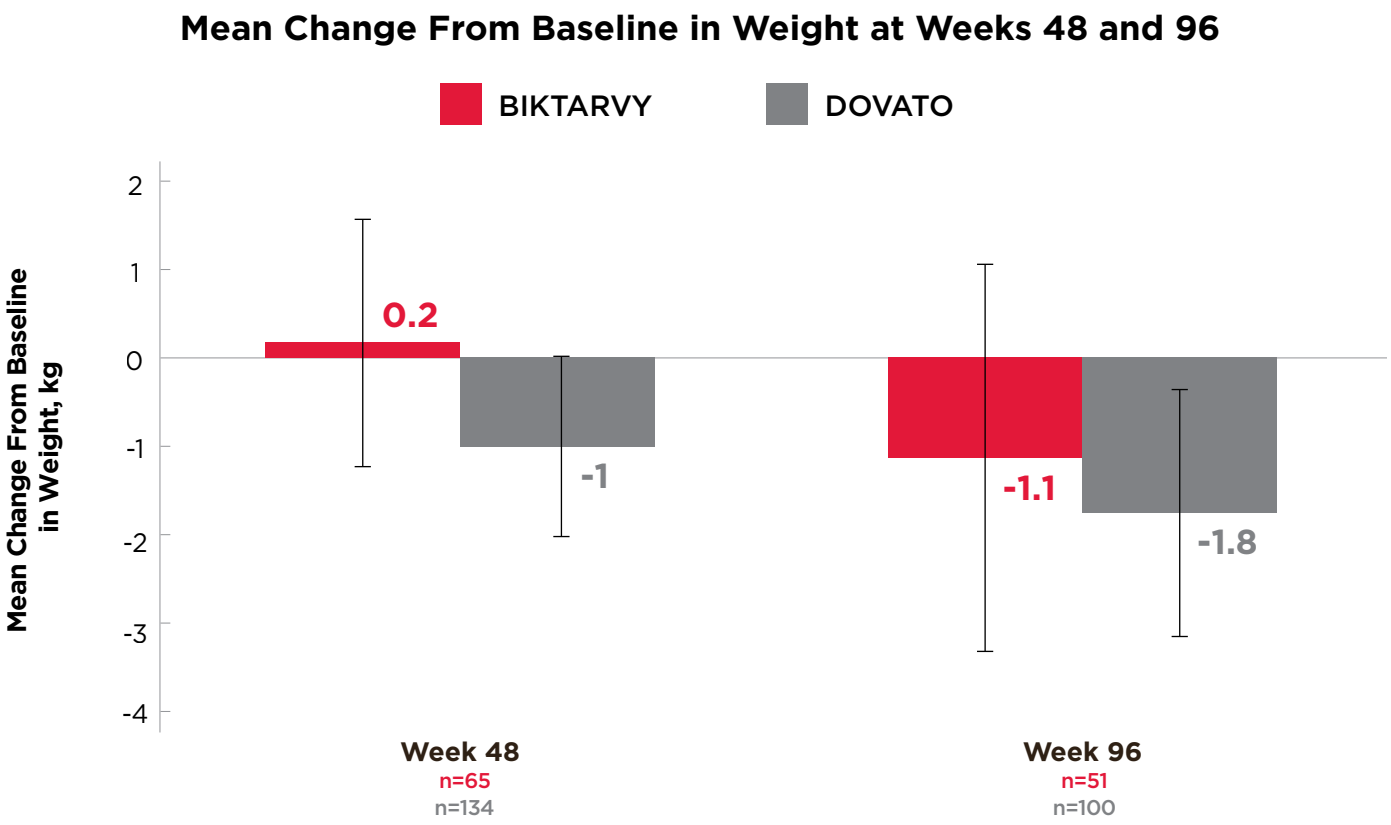
Mean Change From Baseline in Weight at Weeks 48 and 96[1,5]



No difference in mean change from baseline in fasting lipids and weight was observed between BIKTARVY and DOVATO at Weeks 48 and 96[1,5]

Safety and tolerability analyses were summarized using descriptive statistics. The clinical significance of these findings is unknown.[6]

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

PWH, people with HIV; VS, virologically suppressed.

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BIKTARVY® vs FTC/TAF+DTG in VS PWH

Safety Data From Study 4030, a Head-to-Head Study of BIKTARVY vs FTC/TAF+DTG[3]

Study design[3]

- A phase 3, 48-week, randomized, multicenter, double-blind, active-controlled, noninferiority study
- Virologically suppressed (HIV-1 RNA <50 copies/mL) adults (N=565) on DTG plus either FTC/TDF or FTC/TAF were randomized in a 1:1 ratio to switch to BIKTARVY (n=284) or FTC/TAF+DTG (n=281)

Select inclusion criteria[3]

- Documented or suspected NRTI, NNRTI, and PI resistance permitted, including M184V/I resistance mutation

Primary endpoint[3]

- Proportion of adults with HIV-1 RNA ≥50 copies/mL at Week 48 using the FDA snapshot algorithm, 4% noninferiority margin

Select secondary endpoints[3,4]

- Proportion of adults with HIV-RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm
- Safety and tolerability through Week 48, including adverse events and laboratory tests (ie, renal, lipids, weight)

Select study limitation[3,4]

- Safety and tolerability, including adverse events, renal markers, lipids, and weight, were summarized using descriptive statistics. The clinical significance of these findings is unknown

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Primary endpoint results[3]

- Primary endpoint was met at Week 48: 0.4% in the BIKTARVY arm (n=1) and 1.1% in the FTC/TAF+DTG arm (n=3) had HIV-1 RNA ≥50 copies/mL (treatment difference, -0.7%; 95% CI, -2.8% to 1.0%)

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Drugs affecting renal function:** Coadministration of BIKTARVY 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

- **Dosing:** Adult and pediatric patients weighing ≥25 kg: 1 tablet containing 50 mg bictegravir (BIC), 200 mg emtricitabine (FTC), and 25 mg tenofovir alafenamide (TAF) taken once daily with or without food. Pediatric patients weighing ≥14 kg to <25 kg: 1 tablet containing 30 mg BIC, 120 mg FTC, and 15 mg TAF taken once daily with or without food. For these pediatric patients, who are unable to swallow a whole tablet, the tablet can be split and each part taken separately as long as all parts are ingested within approximately 10 minutes.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

CI, confidence interval; DTG, dolutegravir; FDA, US Food and Drug Administration; FTC, emtricitabine; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PWH, people with HIV; RNA, ribonucleic acid; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; VS, virologically suppressed.

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Select Baseline Participant Characteristics[3]

		BIKTARVY (n=284)	FTC/TAF+DTG (n=281)
Age, median (range), years		**51** (22–79)	**50** (20–79)
Age ≥50, n (%)		**157** (55.3)	**151** (53.7)
Sex assigned at birth: female, n (%)		**39** (14)	**41** (15)
Race, n (%)	White	**200** (71)	**199** (72)
	Black	**68** (24)	**61** (22)
	Other	**9** (3)	**13** (5)
	Asian	**3** (1)	**3** (1)
	Native Hawaiian or Pacific Islander	**2** (1)	**1** (<1)
Hispanic/Latino, n (%)		**62** (22)	**49** (18)
eGFR$_{CG}$, median (IQR), mL/min		**97** (79–114)	**100** (83–124)
Weight, median (IQR), kg		**81** (71–93)	**82** (73–95)
CD4 count, median (IQR), cells/μL		**659** (486–885)	**642** (462–791)
NRTI backbone stratum, n (%)	FTC/TAF	**194** (68)	**195** (69)
	FTC/TDF	**90** (32)	**86** (31)

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

CD4, cluster of differentiation 4; DTG, dolutegravir; eGFR$_{CG}$, estimated glomerular filtration rate (Cockcroft-Gault); FTC, emtricitabine; IQR, interquartile range; NRTI, nucleoside reverse transcriptase inhibitor; PWH, people with HIV; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; VS, virologically suppressed.

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BIKTARVY® vs FTC/TAF+DTG in VS PWH

BIKTARVY Has Established Safety Through Week 48[3,4]

Drug-Related AEs Through Week 48

n (%)	BIKTARVY (n=284)	FTC/TAF+DTG (n=281)
Drug-related AEs	**41** (14)	**28** (10)
≥2% in either arm		
Abnormal dreams	**5** (1.8)	**4** (1.4)
Weight increased	**5** (1.8)	**2** (0.7)
Diarrhea	**4** (1.4)	**6** (2.1)
Headache	**4** (1.4)	**6** (2.1)
Drug-related AEs leading to discontinuation	**5** (1.8)	**4** (1.4)

Safety and tolerability analyses were summarized using descriptive statistics. The clinical significance of these findings is unknown.[3,4]

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Renal impairment:** For patients weighing ≥25 kg, not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history. For patients weighing ≥14 kg to <25 kg, not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.

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AE, adverse event; DTG, dolutegravir; FTC, emtricitabine; PWH, people with HIV; TAF, tenofovir alafenamide; VS, virologically suppressed.

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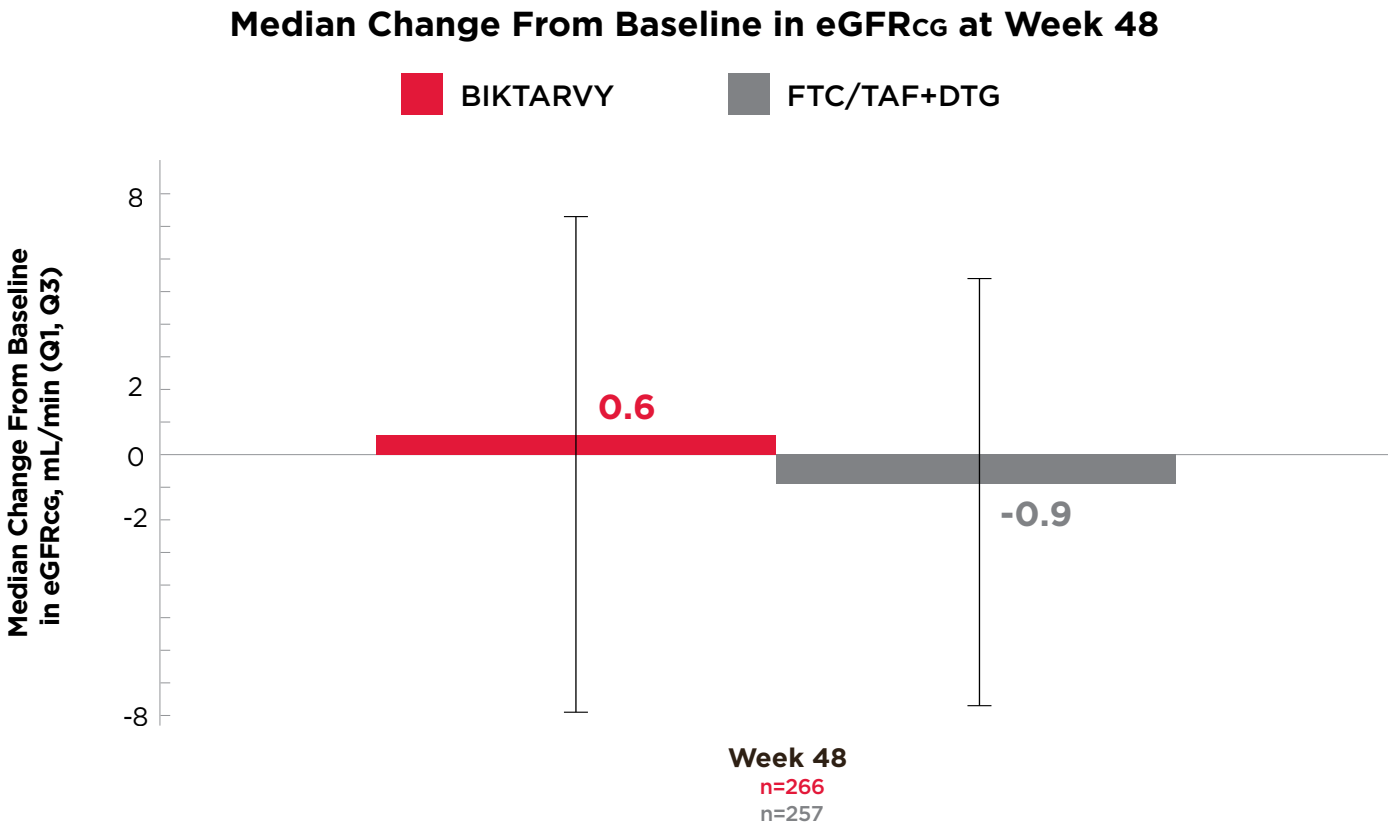
Median Change From Baseline in eGFR at Week 48[3,4]



- Median eGFRCG at baseline was 97 mL/min in the BIKTARVY arm and 100 mL/min in the FTC/TAF+DTG arm[3]

No difference in median change from baseline in eGFR was observed between BIKTARVY and FTC/TAF+DTG at Week 48[3]

Safety and tolerability analyses were summarized using descriptive statistics. The clinical significance of these findings is unknown.[3,4]

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Prior to or when initiating, and during treatment:** As clinically appropriate, 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 on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

DTG, dolutegravir; eGFR, estimated glomerular filtration rate; eGFRCG, estimated glomerular filtration rate (Cockcroft-Gault); FTC, emtricitabine; PWH, people with HIV; Q, quartile; TAF, tenofovir alafenamide; VS, virologically suppressed.

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Median Change From Baseline in Lipid Parameters at Week 48[7]

Median Change From Baseline in Lipid Parameters at Week 48 (Q1, Q3)

	BIKTARVY **Baseline** (n=280) **Week 48** (n=252)	**FTC/TAF+DTG** **Baseline** (n=278) **Week 48** (n=249)
Total-C (mg/dL)	**-1** (-20, 15)	**-1** (-18, 17)
LDL-C (mg/dL)	**+3** (-14, 19)	**+4** (-11, 17)
HDL-C (mg/dL)	**+0** (-4, 4)	**+1** (-4, 5)
Triglycerides (mg/dL)	**+1** (-30, 30)	**+0** (-26, 30)
Total C: HDL-C ratio	**-0.1** (-0.4, 0.4)	**+0.0** (-0.4, 0.4)

- Initiation of lipid-lowering therapy occurred in 5% of PWH in the BIKTARVY arm and 3% of PWH in the FTC/TAF+DTG arm[7]

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals with HIV-1 should be informed of the potential risks of breastfeeding.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

C, cholesterol; DTG, dolutegravir; FTC, emtricitabine; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PWH, people with HIV; Q, quartile; TAF, tenofovir alafenamide; VS, virologically suppressed.

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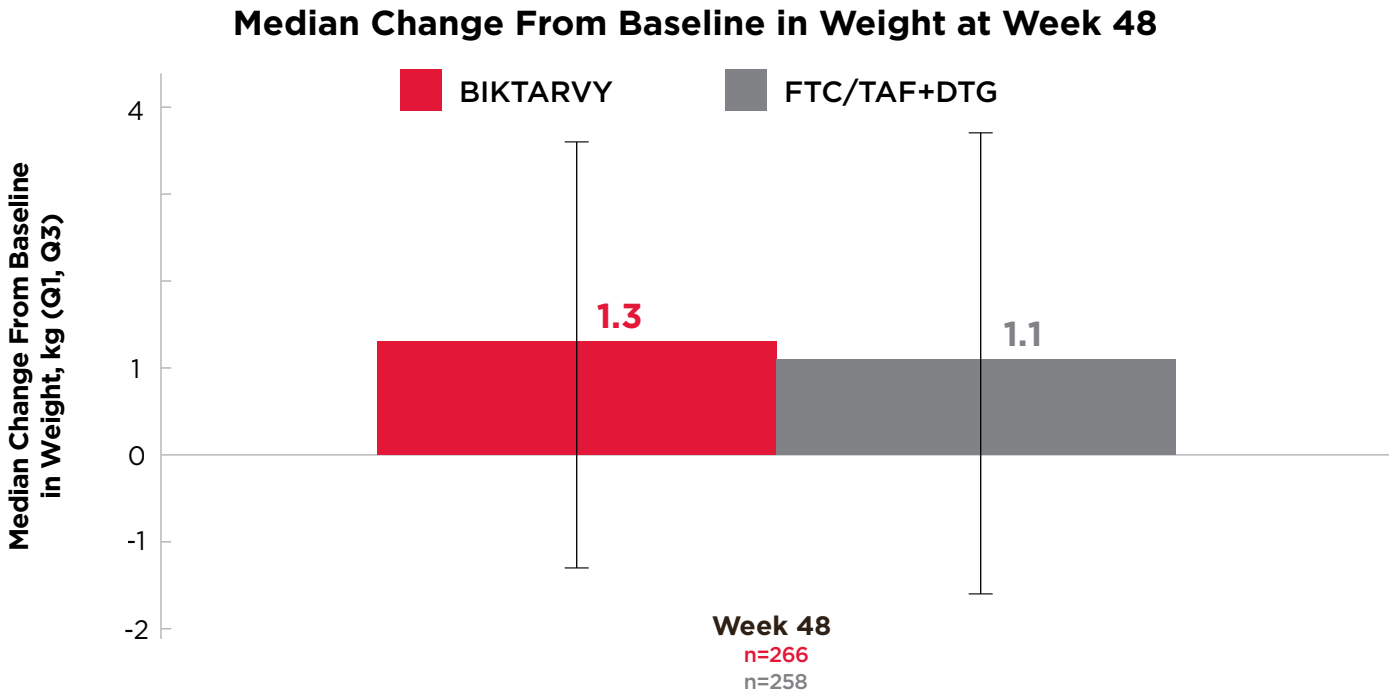
Median Change From Baseline in Weight at Week 48[3,4]



- Median weight at baseline was 81 kg in the BIKTARVY arm and 82 kg in the FTC/TAF+DTG arm[3]
- Numerically greater weight gain was observed at Week 48 in participants switching from TDF-based regimens (+2.2 kg) compared with those remaining on TAF-based regimens (+0.6 kg)[3]

No difference in median change from baseline in fasting lipids and weight was observed between BIKTARVY and FTC/TAF+DTG at Week 48[3]

Safety and tolerability analyses were summarized using descriptive statistics. The clinical significance of these findings is unknown.[3,4]

References: 1. Rolle CP, Castano J, Nguyen V, Hinestrosa F, DeJesus E. Efficacy, safety, and tolerability of switching from bictegravir/emtricitabine/tenofovir alafenamide to dolutegravir/lamivudine among adults with virologically suppressed HIV: the DYAD Study. *Open Forum Infect Dis.* 2024;11(10):ofae560. **2.** BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2025. **3.** Sax PE, Rockstroh JK, Luetkemeyer AF, et al. Switching to bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with human immunodeficiency virus. *Clin Infect Dis.* 2021;73(2):e485-e493. **4.** Data on file. Gilead Sciences, Inc. **5.** Real-world efficacy, safety and persistence of dolutegravir/lamivudine vs. bictegravir/emtricitabine/tenofovir alafenamide among virologically suppressed adults with HIV-results from the 96-week observational extension phase of the DYAD study. Poster presented at: ID Week; October 16–19, 2024; Los Angeles, CA, USA. Poster P-348. **6.** Rolle CP, DeJesus E, et al. Efficacy, safety and tolerability of switching to dolutegravir/lamivudine in virologically suppressed adults living with HIV on bictegravir/emtricitabine/tenofovir alafenamide: the DYAD study. *Orlando Immunology Center clinical protocol OIC_008.* July 29, 2020. **7.** Sax PE, Rockstroh JK, Luetkemeyer AF, et al. Switching to bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with human immunodeficiency virus. *Clin Infect Dis.* 2021;73(2)(supplemental information):e485-e493.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation (cont'd)

- **Lactation:** Individuals with HIV-1 should be informed of the potential risks of breastfeeding.

Please see additional Important Safety Information on the previous pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; PWH, people with HIV; Q, quartile; VS, virologically suppressed.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Head-to-Head Safety Summary[1-3]

From Phase 4 DYAD Study: BIKTARVY® vs DOVATO®[1]

- **Drug-related AEs** through Weeks 48 and 96 were 3% and 5% for BIKTARVY vs 21% and 28% for DOVATO, respectively[1,5]
- **Drug-related AEs leading to withdrawals** through Weeks 48 and 96 were 0% and 0% for BIKTARVY vs 4% and 7% for DOVATO, respectively[1,5]
- **A statistical difference in mean change from baseline in eGFR was observed** between BIKTARVY and DOVATO at both Weeks 48 and 96[1]
  - **Mean change (mL/min/1.73 m²) at Weeks 48 and 96:** BIKTARVY (+0.9, +1) vs DOVATO (-3.4, -4.5)[1,5]
- **No difference in mean change from baseline in fasting lipids and weight was observed** between BIKTARVY and DOVATO at Weeks 48 and 96[1,5]

From Phase 3 Study 4030: BIKTARVY vs FTC/TAF+DTG[2,3]

- **Drug-related AEs** through Week 48 were 14% for BIKTARVY vs 10% for FTC/TAF+DTG[3]
- **Drug-related AEs leading to discontinuations** through Week 48 were 2% for BIKTARVY vs 1% for FTC/TAF+DTG[3]

Safety and tolerability analyses of DYAD and Study 4030 were summarized using descriptive statistics. The clinical significance of these findings is unknown.[6]

INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history; or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir; or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients with HIV-1 and HBV who have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients with HIV-1 and HBV who discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Please see additional Important Safety Information on the previous pages, and click to see full Prescribing Information for BIKTARVY, including BOXED WARNING.

AE, adverse event; DTG, dolutegravir; eGFR, estimated glomerular filtration rate; FTC, emtricitabine; TAF, tenofovir alafenamide.

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BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/ tenofovir alafenamide 25mg tablets