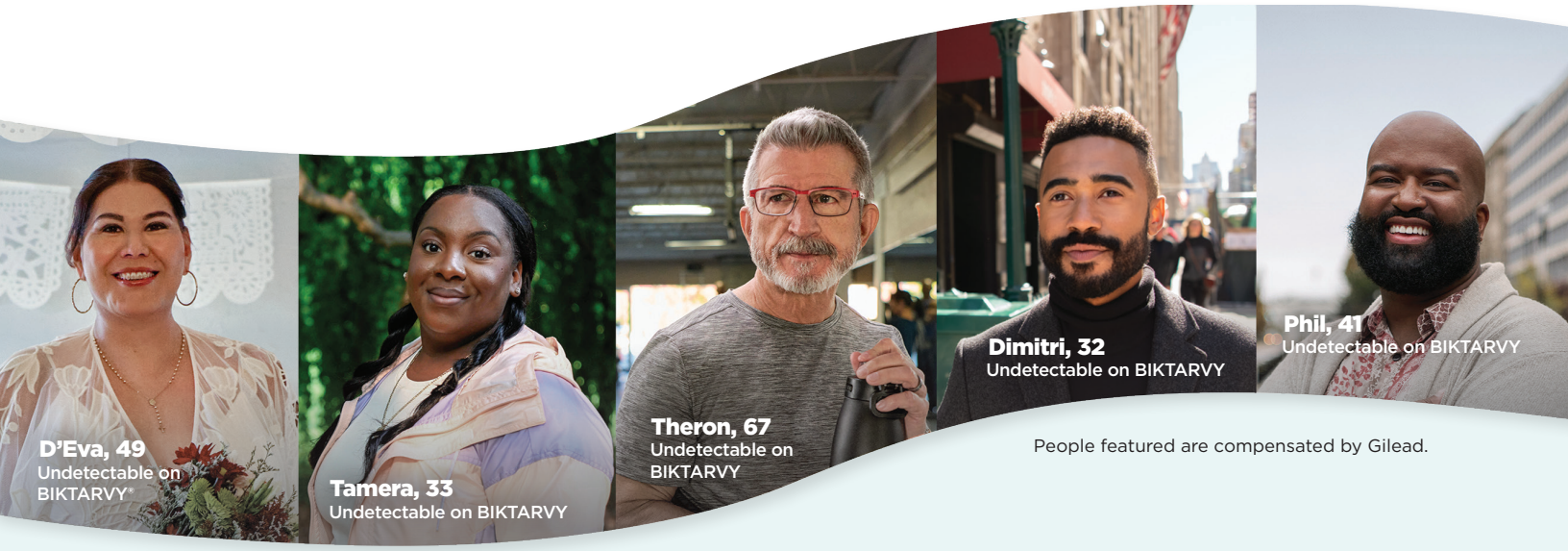
NOW FDA APPROVED:
EXPANDED INDICATION FOR PWH

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

Restarting ANTIRETROVIRAL TREATMENT[1]



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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.

BIKTARVY® is the **first and only STR** to receive an **FDA-approved label expansion for use in PWH with an ART history who are not virologically suppressed**.[1]

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**.

BIKTARVY® has been extensively studied in 9 phase 3 clinical trials across a diverse patient population[1-9]

- **Treatment-Naïve Adults**[1]
- **Virologically Suppressed Adult Women**[4,5]
- **Virologically Suppressed Children and Adolescents (Aged 2 to 17 Years)**[1,7]
- **Virologically Suppressed Adults With ESRD (eGFR <15 mL/min) and on Chronic Hemodialysis**[1,†]

†In Trial 1825, an open-label, single-arm trial, virologically suppressed adults with ESRD (estimated creatinine clearance of <15 mL/min) on chronic hemodialysis were given FTC/TAF in combination with elvitegravir and cobicistat for 96 weeks (n=55). In a 48-week extension, 10 study participants switched to BIKTARVY.[1]

- **Virologically Suppressed Adults**[1-3]
- **Virologically Suppressed Pregnant Adult Women**[1,6,*]

*Studied in a phase 1b clinical trial.[6]

- **Virologically Suppressed Adults, Including Those With Baseline Resistance (NRTI, NNRTI, PI)**[1,8]
- **Virologically Suppressed Adults Aged ≥65 Years**[1,9]
- **Virologically Suppressed Black American Adults, Including Those With Baseline Resistance (NRTI,‡ NNRTI, PI)**[10]

‡Excluding history of K65R/E/N, ≥3 TAMs, or T69 insertions.[10]

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.
- **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.
- **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.

BIKTARVY® is indicated for most people with HIV-1 when STARTING, RESTARTING, or SWITCHING ART[1,11,12]

Differences in Indications for Select HIV Treatment Regimens

	BIKTARVY[1,§] (bictegravir/emtricitabine/tenofovir alafenamide)	DOVATO®[13,§] (dolutegravir/lamivudine)	SYMTUZA®[14,§] (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)	CABENUVA®[15,‖] (cabotegravir/rilpivirine)
	Indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg
TREATMENT-NAÏVE No antiretroviral treatment history	✓	✓	✓	✗
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	✗	✗	✗
VIROLOGICALLY SUPPRESSED To replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen	✓ • with no known or suspected substitutions associated with resistance to bictegravir or tenofovir	✓ • with no history of treatment failure ***and*** • no known substitutions associated with resistance to the individual components of DOVATO	✓ • for at least 6 months ***and*** • have no known substitutions associated with resistance to darunavir or tenofovir	✓ • with no history of treatment failure ***and*** • with no known or suspected resistance to either cabotegravir or rilpivirine

This chart showing indications is not intended to compare clinical effectiveness, safety, tolerability, dosing, or use considerations. Please refer to the full Prescribing Information for each medication, including for information on use in specific populations, warnings and precautions, and clinical data.

RESTARTING ART can be an opportunity to assess a patient's regimen

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

§Pills shown are actual size.
‖Products shown are not actual size.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.
- **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.
- **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

- **Dosage:** 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.

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.
- **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.

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 click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

ART, antiretroviral therapy; ARV, antiretroviral; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; FTC, emtricitabine; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PWH, people with HIV; RNA, ribonucleic acid; STR, single-tablet regimen; TAF, tenofovir alafenamide; TAM, thymidine analogue mutation.

References: 1. BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2025. **2.** Rockstroh J, Molina J-M, Post F, et al. Long-term follow-up after a switch to bictegravir, emtricitabine, tenofovir alafenamide (B/F/TAF) from a boosted protease inhibitor-based regimen. Poster presented at: HIV Drug Therapy Glasgow 2020; October 5-8, 2020; Virtual. Poster P036. **3.** Brar I, Ruane PJ, Berhe M, et al. Efficacy and safety of switch to bictegravir/emtricitabine/tenofovir alafenamide from dolutegravir/abacavir/lamivudine: Results from an open-label extension of a phase 3 randomized, double-blind, multicenter, active-controlled, non-inferiority study. *Medicine (Baltimore)*. 2025;104(8):e41482. **4.** Kityo C, Hagins D, Koenig E, et al. Switching to fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) in virologically suppressed HIV-1 infected women: a randomized, open-label, multicenter, active-controlled, phase 3, noninferiority trial. *J Acquir Immune Defic Syndr*. 2019;82(3):321-328. **5.** Kityo C, Hagins D, Koenig E, et al. Longer-term (96-week) efficacy and safety of switching to bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF) in women. Oral abstract presentation at: International AIDS Society Conference on HIV Science 2019: July 21-24, 2019; Mexico City, Mexico. Abstract MOAB0106. **6.** Zhang H, Hindman JT, Lin L, et al. A study of the pharmacokinetics, safety, and efficacy of bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed pregnant women with HIV. *AIDS*. 2024;38(1):F1-F9. **7.** Natukunda E, Rodriguez CA, McGrath EJ, et al. B/F/TAF in virologically suppressed adolescents and children: two-year outcomes in 6 to <18 year olds and six-month outcomes in toddlers. Abstract presented at: International Workshop on HIV & Pediatrics: July 16-17, 2021; Virtual Abstract 2. **8.** 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. **9.** Maggiolo F, Rizzardini G, Molina J-M, et al. Bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people with HIV aged >65 years: week 48 results of a phase 3b, open-label trial. *Infect Dis Ther*. 2021;10(2):775-788. **10.** Hagins D, Kumar P, Saag M, et al; BRAAVE 2020 Investigators. Switching to bictegravir/emtricitabine/tenofovir alafenamide in Black Americans with HIV-1: a randomized phase 3b, multicenter, open-label study. *J Acquir Immune Defic Syndr*. 2021;88(1):86-95. **11.** Bajema KL, Nance RM, Delaney JAC, et al. Substantial decline in heavily treated therapy-experienced persons with HIV with limited antiretroviral treatment options. *AIDS*. 2020;34(14):2051-2059. **12.** Kagan RM, Baxter JD, Kim T, Marlowe EM. HIV-1 drug resistance trends in the era of modern antiretrovirals: 2018-2024. Poster presented at: Conference on Retroviruses and Opportunistic Infections 2025; Poster 730. **13.** DOVATO. Package insert. ViiV Healthcare; 2024. **14.** SYMTUZA. Package insert. Janssen Pharmaceuticals; 2023. **15.** CABENUVA. Package insert. ViiV Healthcare; 2025.

Insurance or no insurance, click here to see how the Gilead Advancing Access® program may be able to help your patients →

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